# MINISTRY OF HEALTH & FAMILY WELFARE
# National AIDS Control Organization (NACO)
# Government of India

Government of India

## *National AIDS Control Support Project (NACSP)*

## *NATIONAL COMPETITIVE BIDDING*

## BID DOCUMENT

## *For*

## *PROCUREMENT OF METHADONE SYRUP*

## IFB NO.:- SAMS/NACP/Methadone/05/2015

*(Procurement Agent)*

**STRATEGIC ALLIANCE**
**Management Services Pvt. Ltd.**

**1/ 1B, Choudhary Hetram House, Bharat Nagar, New Friends Colony, New Delhi 110025, INDIA;**
**Phone: 011- 8800257774, 9958994797, 011-41653612;**
**Email: pronaco@samsconsult.com**
**Website:** www.samsconsult.com

# MINISTRY OF HEALTH & FAMILY WELFARE
# National AIDS Control Organization
# Government of India

## Through

PROCUREMENT AGENT

**Strategic Alliance Management Services Pvt. Ltd. (SAMS)**
**1/ 1B, Choudhary Hetram House, Bharat Nagar,**
**New Friends Colony, New Delhi 110025, INDIA,**
**Phones: 8800257774, 9958994797, 011-41653612**
**Email: pronaco@samsconsult.com**

# NATIONAL COMPETITIVE BIDDING

## FOR

## *PROCUREMENT OF METHADONE SYRUP (5MG/ML) with Dispensing Bottles*

**Name of the Project : *National AIDS Control Support Project (NACSP)***

**Project Code : P130299**

**Source of Funding : The World Bank**

**BID REFERENCE : SAMS/NACP/Methadone/05/2015**

| | |
|---|---|
| **PERIOD OF SALE OF BID DOCUMENT** | **23.12.2015 to 21.01.2016** |
| **LAST TIME & DATE FOR RECEIPT OF REQUEST FOR CLARIFICATIONS** | **By 1700 hours on 5th January 2016 (All such request must be submitted through mail.) E-mail ID*: pronaco@samsconsult.com*** |
| **TIME & DATE FOR PRE-BID MEETING** | **1500 hours on 12th January 2016** |
| **LAST TIME & DATE FOR RECEIPT OF BIDS** | **1430 hours on 22nd January 2016** |
| **TIME & DATE FOR OPENING OF BIDS** | **1500 hours on 22nd January 2016** |
| **PLACE FOR PRE-BID MEETING, BID SUBMISSION AND BID OPENING** | **Strategic Alliance Management Services Pvt. Ltd. 1/1 B, Choudhary Hetram House, Bharat Nagar, New Friends Colony, New Delhi 110025, INDIA** |
| **All times shown are as per Indian Standard Time (IST)** | |

## CONTENTS

# *INVITATION FOR BIDS*

# INVITATION FOR BIDS (IFB)

| | | |
|---|---|---|
| **Country** | **:** | **India** |
| **Name of Project** | **:** | ***National AIDS Control Support Project (NACSP)*** |
| **Project Code** | **:** | **P130299** |
| **Source of Funding** | **:** | **The World Bank** |
| **Name of Goods** | **:** | **Methadone Syrup (5mg/ml) with Dispensing Bottles** |
| **IFB No.** | **:** | **SAMS/NACP/Methadone/05/2015** |

1. This invitation for bids follows the general procurement notice for this programme that appeared in United Nations *Development Business* (UNDB) Website on 5th May, 2012.

2. Government of India has received fund from the International Development Association (IDA) towards the cost of World Bank assisted **National AIDS Control Support Project** and it is intended that part of the proceeds of this fund will be applied to eligible payments under this proposed project for supply of **1,314 Ltr. of Methadone Syrup *with Dispensing Bottles*** for which this invitation for bid is issued.

3. Strategic Alliance Management Services Pvt. Ltd. (SAMS), acting as procurement agent on behalf of National AIDS Control Organization (NACO), Ministry of Health & Family Welfare (MoH&FW), Govt. of India now invites sealed bids from eligible bidder for the Procurement of **Methadone Syrup *with Dispensing Bottles*.** Further details can be found in the Schedule of Requirements of the bidding documents.

4. Bidding will be conducted through the National Competitive Bidding procedures specified in the World Bank's Guidelines: *Procurement under IBRD Loans and IDA Credits* [January 2011 and revised July, 2014].

5. Interested eligible Bidders may obtain further information from SAMS and inspect the bidding documents at the address given below in S. No 9 between 1000 to 1600 hrs. (IST) on all working days.

6. A complete set of bidding documents in English may be purchased by interested bidders on the submission of a written application to the address below and upon payment of a non-refundable fee of **Rs. 1,000/- or US $20/-.** The document may be purchased from 23rd December, 2015 to 21st January, 2016 from the address mentioned in Para 9 below. The document will be sent by courier on payment of an extra amount of Rs 500/- if requested by mail.

   Bidders can also download the bid document from *websites of SAMS, NACO and Central Public Procurement Portal (CPPP) i.e. www.naco.gov.in or http://www.samsconsult.com/procurement.php. or http://eprocure.gov.in/cppp/.* ***The bidders who have downloaded the bid document from websites are also required to submit non-refundable bid document fee of Rs.1,000/- or US $ 20/- as the case may be along with their bid.*** *The bid document fee*

*payment can be made by Demand Draft/ Cashier's Cheque / Certified Cheque in favour of* ***Strategic Alliance Management Services Pvt. Ltd. payable at Delhi (India).***

7. *SAMS will only evaluate the bids accompanied by the Bid Document Fees, as stated in Paras 5 & 6, above.*

8. The bidders, who have downloaded the bid documents, shall be solely responsible for checking these websites for any addendum/amendment issued subsequently to the bid document and take the same into consideration while preparing and submitting the bids.

9. Bids must be delivered to the address given below before **1430 hrs (IST) on** 22nd **January, 2016**. **All bids must be accompanied by Bid Document Fee as mentioned above in para 6 and Bid Security as specified in the "Section VI – Schedule of Requirements" of the bidding document.** Late bids will be rejected. Bids will be opened in the presence of the bidders' representatives, who choose to attend the bid opening at the address below **at 1500 hrs (IST) on 22nd January, 2016**.

**Strategic Alliance Management Services Pvt. Ltd., (SAMS)**
**1/1 B, Choudhary Hetram House, Bharat Nagar,**
**New Friends Colony, New Delhi 110025, INDIA**
**Phones: 8800257774, 9958994797, 011-41653612**
**Email: pronaco@samsconsult.com**

**Sanjay Rastogi**
**Associate Director (MCS)**

# SECTION- I

# INSTRUCTIONS TO BIDDERS

## TABLE OF CLAUSES

# Instructions to Bidders

## A. INTRODUCTION

**1. Scope of Bid**

1.1 The Purchaser, as specified in the **Bid Data Sheet** and in the Special Conditions of Contract (SCC), invites bids for the supply of Goods (pharmaceuticals, vaccines, contraceptives, or nutritional supplements as specified in the **Bid Data Sheet**) described in the Schedule of Requirements. The name and identification number of the Contract is provided in the **Bid Data Sheet** and in the SCC.

1.2 Throughout these bidding documents, the terms "writing" means any type written, or printed communication, including e-mail, telex, cable, and facsimile transmission, and "day" means calendar day. Singular also means plural.

**2. Source of Funds**

2.1 The Borrower named in the **Bid Data Sheet** has applied for or received a loan or credit (as identified with the loan/credit number in the **Bid Data Sheet** and called a "loan" in these Bidding Documents) from the International Bank for Reconstruction and Development or from the International Development Association (interchangeably called "the Bank" in these Bidding Documents) equivalent to the amount in U.S. dollars indicated in the **Bid Data Sheet** toward the cost of the Project named in the **Bid Data Sheet.** The Borrower intends to apply a part of the proceeds of this loan to eligible payments under the Contract for which these bidding documents are issued.

2.2 Payment by the Bank will be made only at the request of the Borrower and upon approval by the Bank in accordance with the terms and conditions of the Loan Agreement, and will be subject in all respects to the terms and conditions of that Agreement. The Loan Agreement prohibits a withdrawal from the loan account for the purpose of any payment to persons or entities, or for any import of Goods, if such payment or import, to the knowledge of the Bank, is prohibited by a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. No party other than the Borrower shall derive any rights from the Loan Agreement or have any claim to the loan proceeds.

**3. Fraud and Corruption**

3.1 It is the Bank's policy to require that Borrowers (including beneficiaries of Bank loans), as well as bidders, suppliers, and contractors and their subcontractors under Bank-financed contracts, observe the highest standard of ethics during the procurement and execution of such contracts.[1] In pursuance of this policy, the Bank:

(a) defines, for the purposes of this provision, the terms set forth below as follows:

(i) "corrupt practice"[2] is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(ii) "fraudulent practice"[3] is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii) "collusive practice"[4] is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

(iv) "coercive practice"[5] is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(v) "obstructive practice" is

(aa) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank

[1] In this context, any action taken by a bidder, supplier, contractor, or a sub-contractor to influence the procurement process or contract execution for undue advantage is improper.

[2] "Another party" refers to a public official acting in relation to the procurement process or contract execution]. In this context, "public official" includes World Bank staff and employees of other organizations taking or reviewing procurement decisions.

[3] A "party" refers to a public official; the terms "benefit" and "obligation" relate to the procurement process or contract execution; and the "act or omission" is intended to influence the procurement process or contract execution.

[4] "Parties" refers to participants in the procurement process (including public officials) attempting to establish bid prices at artificial, non competitive levels.

[5] A "party" refers to a participant in the procurement process or contract execution.

investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(bb) acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under sub-clause 3.1 (e) below.

(b) will reject a proposal for award if it determines that the bidder recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;

(c) will cancel the portion of the loan allocated to a contract if it determines at any time that representatives of the Borrower or of a beneficiary of the loan engaged in corrupt, fraudulent, collusive, or coercive practices during the procurement or the execution of that contract, without the Borrower having taken timely and appropriate action satisfactory to the Bank to address such practices when they occur;

(d) will sanction a firm or individual, including declaring ineligible, either indefinitely or for a stated period of time, to be awarded a Bank-financed contract if it at any time determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a Bank-financed contract; and

(e) will have the right to require that a provision be included in bidding documents and in contracts financed by a Bank loan, requiring bidders, suppliers, and contractors and their sub-contractors to permit the Bank to inspect their accounts and records and other documents relating to the bid submission and contract performance and to have them audited by auditors appointed by the Bank.

3.2 Furthermore, bidders shall be aware of the provision stated in Sub-Clauses 5.4 and 23.1 (d) of the General

Conditions of Contract.

3.3 In pursuance of the policy defined in ITB Sub-Clause 3.1, the Bank will cancel the portion of the loan allocated to a Contract for Goods or works if it at any time determines that corrupt or fraudulent practices were engaged in by the representatives of the Borrower or of a beneficiary of the loan during the procurement or the execution of that Contract, without the Borrower having taken timely and appropriate action satisfactory to the Bank to remedy the situation.

**4. Eligibility**

4.1 Except as provided in ITB Sub-Clauses 4.2 and 4.3, this bidding process is open to qualified (prequalified or not) firms from any country, pursuant to the Guidelines: Procurement under IBRD Loans and IDA Credits herein referred to as the Procurement Guidelines.

4.2 Firms of a member country may be excluded from bidding if:

(a) either: (i) as a matter of law or official regulation, the Borrower's country prohibits commercial relations with that country, provided that the Bank is satisfied that such exclusion does not preclude effective competition for the supply of the Goods required; or (ii) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Borrower's country prohibits any import of Goods from that country or any payments to persons or entities in that country.

(b) a firm has been engaged by (i) the Borrower or (ii) the Purchaser or (iii) a Purchasing Agent that has been duly authorized to act on behalf of the Borrower or Purchaser to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the Goods described in these Bidding Documents.

(c) government-owned enterprises in the Borrower's country may participate only if they can establish that they (i) are legally and financially autonomous and (ii) operate under commercial law. No dependent agency of the Borrower or Sub-Borrower under a Bank-financed project

shall be permitted to bid or submit a proposal for the procurement of Goods under the project.

4.3 A firm declared ineligible by the Bank in accordance with ITB Sub-Clause 3.1 (c) shall be ineligible to bid for a Bank-financed contract during the period of time determined by the Bank.

4.4 A firm that has been determined to be ineligible by the Bank in relation to the Bank Guidelines On Preventing and Combating Fraud and Corruption in Projects Financed by IBRD Loans and IDA Credits and Grants shall be not be eligible to be awarded a contract.

4.4 Pursuant to ITB Sub-Clause 14.1, the Bidder shall furnish, as part of its bid, documents establishing, to the Purchaser's satisfaction, the Bidder's eligibility to bid.

4.5 Bidders shall provide such evidence of their continued eligibility satisfactory to the Purchaser as the Purchaser shall reasonably request.

**5. Eligible Goods and Services**

5.1 Funds from Bank loans are disbursed only on account of expenditures for the Goods and Services, provided by nationals of, and produced in or supplied from eligible source countries as defined in the edition of the Procurement Guidelines specified in the **Bid Data Sheet** and in Section III. Goods produced or Services supplied from a Bank member country may be excluded if that member country is subject to the conditions specified in ITB Sub-Clause 4.2 (a) (i) or (ii).

5.2 For purposes of this clause, the nationality of the bidder is distinct from the country from where the Goods and Services are supplied.

5.3 For purposes of this clause, (a) the term "Goods" includes any Goods that are the subject of this Invitation for Bids and (b) the term "Services" includes related services such as transportation, insurance, commissioning, and training.

**6. Documents Establishing Eligibility of Goods and Services and Conformity to**

6.1 Pursuant to ITB Clause 14, the Bidder shall furnish, as part of its bid, documents establishing, to the Purchaser's satisfaction, the eligibility of the Health Sector Goods and services to be supplied under the Contract.

**Bidding Documents**

6.2 The documentary evidence of the eligibility of the Goods and Services shall consist of a statement in the Price Schedule of the country of origin of the Goods and Services offered that shall be confirmed by a certificate of origin issued at the time of shipment.

6.3 The documentary evidence of conformity of the Goods and Services to the Bidding Documents may be in the form of literature, drawings, and data and shall consist of:

(a) a detailed description of the essential technical and performance characteristics of the Goods;

(b) an item-by-item commentary on the Purchaser's Technical Specifications demonstrating substantial responsiveness of the Goods and Services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications;

(c) any other procurement-specific documentation requirement as stated in the **Bid Data Sheet.**

6.4 Unless the **Bid Data Sheet** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in the Purchaser's country. A Bidder who has already registered its Goods by the time of bidding should submit a copy of the Registration Certificate with its bid. Otherwise, the successful Bidder, by the time of Contract signing, shall submit to the Purchaser either:

(a) a copy of the Registration Certificate of the Goods for use in the Purchaser's country.

OR, if such Registration Certificate has not yet been obtained,

(b) evidence establishing to the Purchaser's satisfaction that the Bidder has complied with all the documentary requirements for registration as specified in the **Bid Data Sheet.**

6.4.1 The Purchaser shall at all times cooperate with the successful Bidder to facilitate the registration process within the Purchaser's country. The agency and contact person able to provide additional information about registration are

identified in the **Bid Data Sheet.**

6.4.2 If the Goods of the successful Bidder have not been registered in the Purchaser's country at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.

6.5 For purposes of the commentary to be furnished pursuant to ITB Clause 6.3 (b) above, the Bidder shall note that standards as well as references to brand names designated by the Purchaser in its Technical Specifications are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalog numbers in its bid, provided that it demonstrates to the Purchaser's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.

**7. Qualifications of the Bidder**

7.1 The Bidder shall provide documentary evidence to establish to the Purchaser's satisfaction that:

(a) the Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified in the **Bid Data Sheet,** and has a successful performance history in accordance with criteria specified in the **Bid Data Sheet.** If a prequalification process has been undertaken for the Contract, the Bidder shall, as part of its bid, update any information submitted with its application for prequalification.

(b) in the case of a Bidder offering to supply Health Sector Goods, identified in the Bid Data Sheet, that the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the manufacturer or producer of such Goods to supply the Goods in the Purchaser's country;

(c) in the case of a Bidder who is not doing business within the Purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the Bidder is or will be (if awarded the Contract) represented by a local service/maintenance provider in the Purchaser's country equipped and able to carry out the Bidder's warranty obligations prescribed

in the Conditions of Contract and/or Technical Specifications; and

(d) the Bidder meets the qualification criteria listed in the **Bid Data Sheet** (see additional clauses of Bid Data Sheet for pharmaceuticals).

**8. One Bid per Bidder**

8.1 A firm shall submit only one bid either individually or as a partner of a joint venture (other than in cases of alternatives pursuant to ITB Clause 20). A firm that submits either individually or, as a member of a joint venture, more than one bid will cause all the proposals with the firm's participation to be disqualified.

**9. Cost of Bidding**

9.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

## B. THE BIDDING DOCUMENTS

**10. Content of Bidding Documents**

10.1 The Bidding Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITB Clause 12.

Section I. Instructions to Bidders (ITB)
Section II. Bid Data Sheet (BDS)
Section III Eligibility
Section IV. General Conditions of Contract (GCC)
Section V. Special Conditions of Contract (SCC)
Section VI. Schedule of Requirements
Section VII. Technical Specifications
Section VIII. Sample Forms (including Contract Agreement)

10.2 The "Invitation for Bids" does not form part of the Bidding Documents and is included as a reference only. In case of discrepancies between the Invitation for Bid and the Bidding Documents listed in 10.1 above, said Bidding Documents will take precedence.

**11. Clarification of Bidding Documents**

11.1 A prospective Bidder requiring any clarification of the Bidding Documents shall contact the **Purchaser** in writing or by cable (for these ITB, the term "cable" is deemed to include electronic mail or facsimile) at the **Purchaser's** address **indicated in the Bid Data Sheet.** The **Purchaser** will respond **in writing to any request**

**for clarification received no later than fourteen (14) calendar days** prior to the deadline of submission of bids. Copies of the Purchaser's response shall be sent to all prospective Bidders who have purchased the Bidding Documents, including a description of the inquiry but without identifying its source.

**12. Amendment of Bidding Documents**

12.1 At any time prior to the deadline for submission of bids, the Purchaser may amend the Bidding Documents by issuing Addenda.

12.2 Any addendum thus issued shall be part of the Bidding Documents pursuant to ITB Sub-Clause 10.1 and shall be communicated in writing to all purchasers of the Bidding Documents and will be binding on them. Bidders are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the amendment will have been taken into account by the Bidder in its bid.

12.3 To give prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the Purchaser shall extend, at its discretion, the deadline for submission of bids, in which case, the Purchaser will notify all Bidders by cable confirmed in writing of the extended deadline.

## C. PREPARATION OF BIDS

**13. Language of Bid**

13.1 The bid, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Purchaser, shall be written in the language specified in the **Bid Data Sheet.** Supporting documents and printed literature furnished by the Bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified**,** in which case, for purposes of interpretation of the Bid, the translation shall govern.

**14. Documents Constituting the Bid**

14.1 The bid submitted by the Bidder shall comprise the following:

(a) duly filled-in Form of Bid and Price Schedule, in accordance with the forms indicated in Section VIII;

(b) original form of bid security in accordance with the provisions of ITB Sub-Clause 19 (Bid Security);

(c) alternative offers, at the Bidder's option, when permitted;

(d) written power of attorney authorizing the signatory of the bid to commit the Bidder;

(e) in the absence of prequalification, documentary evidence in accordance with ITB Sub-Clause 4.4 establishing to the Purchaser's satisfaction the Bidder's eligibility to bid including but not limited to documentary evidence that the Bidder is legally incorporated in a territory of an eligible source country as defined under ITB Clause 4;

(f) documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITB Clause 6 that the Goods and ancillary services to be supplied by the Bidder are eligible Goods and Services, pursuant to ITB Clause 5, and that they conform to the Bidding Documents;

(g) documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITB Clause 7 that the Bidder is qualified to perform the Contract if its bid is accepted. In the case where prequalification of Bidders has been undertaken, and pursuant to ITB Paragraph 7.1 (a) the Bidder must provide evidence on any changes in the information submitted as the basis for prequalification, or if there has been no change at all in said information, a statement to this effect;

(h) any other documentation as requested in the **Bid Data Sheet.**

**15. Bid Form**

15.1 The Bidder shall complete the Bid Form and the appropriate Price Schedule furnished in the Bidding Documents, indicating the Goods to be supplied, a brief description of the Goods, their country of origin, quantity, and prices.

**16. Bid Prices**

16.1 Prices shall be quoted as specified in each Price Schedule included in Section VIII, Sample Forms. The dis-aggregation of price components is required solely for the purpose of facilitating the comparison of bids by the Purchaser. This shall not in any way limit the

Purchaser's right to contract on any of the terms offered. In quoting prices, the Bidder shall be free to use transportation through carriers registered in any eligible country, in accordance with Section III Eligible Countries. Similarly, the Bidder may obtain insurance services from any eligible country in accordance with Section III Eligible Countries.

16.2 Prices shall be entered in the following manner:

(i) the price of the Goods quoted EXW (ex works, ex factory, ex warehouse, ex showroom, or off-the-shelf, as applicable), including all customs duties and sales and other taxes already paid or payable on the components and raw material used in the manufacture or assembly of the Goods;

(ii) any Purchaser's Country sales tax and other taxes which will be payable on the Goods if the contract is awarded to the Bidder; and

(iii) the price for inland transportation, insurance, and other local services required to convey the Goods to their final destination specified in the **Bid Data Sheet.**

16.3 The terms EXW, CIF, CIP, etc., shall be governed by the rules prescribed in the current edition of *Incoterms* published by the International Chamber of Commerce, Paris.

16.4 The Bidder's separation of price components in accordance with ITB Clause 16.2 above will be solely for the purpose of facilitating the comparison of bids by the Purchaser and will not in any way limit the Purchaser's right to contract on any of the terms offered.

16.5 Unless otherwise specified in the **Bid Data Sheet,** prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as nonresponsive and will be rejected, pursuant to ITB Clause 29. If, however, in accordance with the **Bid Data Sheet,** prices quoted by the Bidder shall be subject to adjustment during the performance of the Contract, a bid submitted with a fixed price quotation will not be rejected, but the price will not

be adjusted.

16.6 Pursuant to Sub-Clause 16.1 above, and if so indicated in the **Bid Data Sheet,** bids are being invited for one or more items, or for individual Contracts (lots) each comprising at least eighty percent (100%) of the total number of items required under the lot. In both cases, each item offered must comprise the full quantity required under that item. Bidders wishing to offer any price reduction for the award of more than one Contract shall specify in their bid the price reductions applicable to each package or, alternatively, to individual Contracts within the package. Price reductions may be submitted as an amount or a percentage to be applied to the bid prices.

**17. Currencies of Bid**

17.1 The Bidder shall express its prices for goods and related services to be supplied in the currency of the Purchaser's country.

**18. Period of Validity of Bids**

18.1 Bids shall remain valid for the period stipulated in the **Bid Data Sheet** after the date of bid submission specified in ITB Clause 23. A bid valid for a shorter period shall be rejected by the Purchaser as nonresponsive.

18.2 In exceptional circumstances, prior to expiry of the original bid validity period, the Purchaser may request that the Bidders extend the period of validity for a specified additional period. The request and the responses thereto shall be made in writing. A Bidder may refuse the request without forfeiting its bid security. Except as provided in ITB Clause 18.3, a Bidder agreeing to the request will not be required or permitted to modify its bid, but will be required to extend the validity of its bid security for the period of the extension.

18.3 In the case of fixed price contracts, if the award is delayed by a period exceeding fifty-six (56) days beyond the expiry of the first bid validity extension, the contract price will be increased by a factor that reflects changes in the cost of inputs specified in the request for second and subsequent extensions.

**19. Bid Security**

19.1 If required, in the **Bid Data Sheet,** the Bidder shall furnish, as part of its bid, a bid security as specified in the **Bid Data Sheet,** or a Bid Securing Declaration. The amount of the Bid Security shall be as stipulated

in the **Bid Data Sheet** in the currency of the Purchaser's country.

19.2 The bid security shall remain valid for a period of 28 days beyond the validity period for the bid, and beyond any extension subsequently requested under Sub-clause 18.2.

19.3 The bid security shall, at the Bidder's option, be in the form of either a letter of credit or a bank guarantee from a reputable banking institution, or a bond issued by a surety selected by the Bidder and located in any country. If the institution issuing the bond is located outside the purchaser's country, it shall have a correspondent financial institution located in the purchaser's country to make it enforceable. The format of the bank guarantee/bond shall be in accordance with the forms included in the bidding documents; other formats may be permitted, subject to the prior approval of the Purchaser.

19.4 Any bid not accompanied by an acceptable bid security shall be rejected by the Purchaser as nonresponsive. The bid security of a joint venture must be in the name of the joint venture submitting the bid.

19.5 The bid securities of unsuccessful Bidders will be returned as promptly as possible.

19.6 The bid security of the successful Bidder will be returned when the Bidder has signed the Contract and furnished the required performance security.

19.7 The bid security may be forfeited

(a) if the Bidder withdraws its bid, except as provided in ITB Sub-Clauses 18.2 and 25.3; or

(b) in the case of a successful bidder, if the Bidder fails within the specified time limit to:

(i) sign the contract, or

(ii) furnish the required performance security.

19.8 If a bid security is **not required in the BDS**, and

(a) if a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Letter of Bid Form, except as provided in ITB 18.2, or

(b) if the successful Bidder fails to: sign the Contract in accordance with ITB 39; or furnish a performance security in accordance with ITB 40;

the Borrower may**, if provided for in the BDS,** declare the Bidder disqualified to be awarded a contract by the Employer for a period of time **as stated in the BDS**.

**20. Alternative Bids by Bidders**

20.1 Unless **specified in the Bid Data Sheet,** alternative bids shall not be accepted.

**21. Format and Signing of Bid**

21.1 The Bidder shall prepare an original and the number of copies/sets of the bid indicated in the **Bid Data Sheet,** clearly marking each one as "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern.

21.2 The original and all copies of the bid, each consisting of the documents listed in ITB Sub-Clause 14.1, shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the Contract. The later authorization shall be indicated by written power of attorney, which pursuant to ITB Sub-Clause 14.1 (d) shall accompany the bid.

21.3 Any interlineations, erasures, or overwriting to correct errors made by the Bidder should be initialed by the person or persons signing the bid.

21.4 The Bidder shall furnish in the Bid Form (a sample of which is provided in the Sample Forms Section of the Bidding Documents) information regarding commissions or gratuities, if any, paid or to be paid to agents relating to this bid and to the execution of the Contract if the Bidder is awarded the Contract.

## D. SUBMISSION OF BIDS

**22. Sealing and Marking of Bids**

22.1 Bidders may always submit their bids by mail or by hand. When so specified in the **Bid Data Sheet,** bidders shall have the option of submitting their bids electronically.

(a) The Bidder shall enclose the original and each copy of the bid including alternative bids, if

permitted in accordance with ITB Clause 20, in separate sealed envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." The envelopes containing the original and copies shall then be enclosed in another envelope.

(b) Bidders submitting bids electronically shall follow the electronic bid submission procedures specified in the **Bid Data Sheet**

22.2 The inner and outer envelopes shall:

(a) bear the name and address of the Bidder;

(b) be addressed to the Purchaser at the address given in the **Bid Data Sheet;**

(c) bear the specific identification of this bidding process indicated in the **Bid Data Sheet,** the Invitation for Bids (IFB) title and number indicated in the **Bid Data Sheet;** and

(d) bear a statement "DO NOT OPEN BEFORE [date and time]" to be completed with the time and date specified in the Bid Data Sheet relating to ITB Sub-Clause 23.1.

22.3 If the outer envelope is not sealed and marked as required by ITB Sub-Clause 22.2, the Purchaser will assume no responsibility for the misplacement or premature opening of the bid.

**23. Deadline for Submission of Bids**

23.1 Bids must be received by the Purchaser at the address specified in the **Bid Data Sheet** relating to ITB Sub-Clause 22.2 (b) no later than the time and date specified in the **Bid Data Sheet.**

23.2 The Purchaser may, at its discretion, extend the deadline for the submission of bids by amending the Bidding Documents in accordance with ITB Sub-Clause 12.3, in which case all rights and obligations of the Purchaser and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

**24. Late Bids**

24.1 Any bid received by the Purchaser after the deadline for submission of bids prescribed by the Purchaser in the **Bid Data Sheet** pursuant to ITB Clause 23 will be rejected and returned unopened to the Bidder.

**25. Modification and Withdrawal of Bids**

25.1 The Bidder may modify or withdraw its bid after submission, provided that written notice of the modification, or withdrawal of the bids duly signed by an authorized representative, is received by the Purchaser prior to the deadline prescribed for submission of bids.

25.2 The Bidder's modification shall be prepared, sealed, marked, and dispatched as follows:

(a) The Bidder shall provide an original and the number of copies specified in the **Bid Data Sheet** of any modifications to its bid, clearly identified as such, in two inner envelopes duly marked "BID MODIFICATION-ORIGINAL" and "BID MODIFICATION-COPIES." The inner envelopes shall be sealed in an outer envelope, which shall be duly marked "BID MODIFICATION."

(b) Other provisions concerning the marking and dispatch of bid modifications shall be in accordance with ITB Sub-Clauses 22.2 and 22.3.

25.3 A Bidder wishing to withdraw its bid shall notify the Purchaser in writing prior to the deadline prescribed for bid submission. A withdrawal notice shall be received prior to the deadline for submission of bids. The notice of withdrawal shall:

(a) be addressed to the Purchaser at the address named in the **Bid Data Sheet,**

(b) bear the specific identification of the bidding process (Contract name), the IFB title and IFB number, and the words "BID WITHDRAWAL NOTICE," and

(c) be accompanied by a written power of attorney authorizing the signatory of the withdrawal notice to withdraw the bid.

25.4 Bids requested to be withdrawn in accordance with ITB Sub-Clause 25.3, shall be returned unopened to the Bidders.

25.5 No bid may be withdrawn in the interval between the bid submission deadline and the expiration of the bid validity period specified in ITB Clause 18. Withdrawal of a bid during this interval may result in the forfeiture of the Bidder's bid security, pursuant to ITB Sub-

Clause 19.7.

## E. Opening and Evaluation of Bids

**26. Bid Opening**

26.1 The Purchaser will open all bids, including withdrawal notices and modifications, in public, in the presence of Bidders' representatives who choose to attend, at the time, on the date, and at the place specified in the **Bid Data Sheet.** Any specific electronic bid opening procedures required if electronic bidding is permitted in accordance with ITB Clause 22.1, shall be as specified in the **Bid Data Sheet**. Bidders' representatives shall sign a register as proof of their attendance.

26.2 Envelopes marked "WITHDRAWAL" shall be read out and the envelope with the corresponding bid shall not be opened but returned to the Bidder. No bid withdrawal notice shall be permitted unless the corresponding withdrawal notice is read out at bid opening. Envelopes marked "MODIFICATION" shall be read out and opened with the corresponding bid.

26.3 Bids shall be opened one at a time, reading out: the name of the Bidder and whether there is a modification; the bid price of each item or lot, as the case may be, including discounts and alternative offers, if allowed in the Bid Data Sheet; the presence or absence of a bid security, if required; the presence or absence of requisite powers of attorney; and any other such details as the Purchaser may consider appropriate. No bid shall be rejected at bid opening except for late bids pursuant to Sub-Clause 24.1.

26.4 Bids (and modifications sent pursuant to ITB Sub-Clause 25.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances.

26.5 The Purchaser will prepare minutes of the bid opening at the end of the opening session, including, as a minimum: the name of the Bidder and whether there was a withdrawal or modification; the bid price; including any discounts or alternatives offered if permitted in the Bid Data Sheet; the presence or absence of a bid security; the presence or absence of

requisite powers of attorney.

26.6 The Bidder's representatives who are present shall be requested to sign the minutes. The omission of a Bidder's signature on the minutes shall not invalidate the content and effect of the minutes. The minutes should be distributed to all Bidders who request them.

**27. Clarification of Bids**

27.1 During evaluation of the bids, the Purchaser may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted, except to correct arithmetic errors identified by the Purchaser in the evaluation of the bids, in accordance with ITB Sub-Clause 30.1.

**28. Confidentiality**

28.1 Information relating to the examination, clarification, evaluation, and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the notification of Contract award is made to all Bidders.

28.2 Any effort by the bidder to influence the Purchaser in the Purchaser's bid evaluation, bid comparison, or contract award decisions may result in the rejection of the Bidder's bid.

28.3 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Purchaser on any matter related to its bid, it should do so in writing.

**29. Examination of Bids and Determination of Responsiveness**

29.1 The Purchaser will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed, and whether the bids are generally in order. In the case where a prequalification process has been undertaken for the Contract(s) for which these Bidding Documents have been issued, the Purchaser will ensure that each bid is from a prequalified Bidder.

29.2 The Purchaser may waive any minor informality, nonconformity, or irregularity in a bid that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any

Bidder.

29.3 Prior to the detailed evaluation, pursuant to ITB Clause 32, the Purchaser will determine whether each bid is of acceptable quality, is complete, and is substantially responsive to the Bidding Documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviations, exceptions, objections, conditionalities, or reservations. A material deviation, exception, objection, conditionality, or reservation is one: (i) that limits in any substantial way the scope, quality, or performance of the Goods and related Services; (ii) that limits, in any substantial way that is inconsistent with the Bidding Documents, the Purchaser's rights or the successful Bidder's obligations under the Contract; and (iii) that the acceptance of which would unfairly affect the competitive position of other Bidders who have submitted substantially responsive bids.

29.4 If a bid is not substantially responsive, it will be rejected by the Purchaser and may not subsequently be made responsive by the Bidder by correction of the nonconformity. The Purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself.

**30. Correction of Errors**

30.1 Arithmetical errors will be rectified as follows. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit or subtotal price shall prevail. If there is a discrepancy between subtotals and the total price, the total price shall be corrected. If there is a discrepancy between words and figures, the amount in words will prevail. If a Bidder does not accept the correction of errors, its bid will be rejected.

**31. Conversion to Single Currency**

31.1 To facilitate evaluation and comparison, the Purchaser will convert all bid prices expressed in the various currencies in which they are payable to either:

(a) the currency of the Purchaser's country at the selling exchange rate established for similar transactions by the Central Bank or a commercial bank in the Purchaser's country.

**or**

(b) a currency widely used in international trade, such as U.S. dollars, at the selling rate of exchange published in the international press for the amount payable in foreign currency; and at the selling exchange rate established for similar transactions by the Central Bank in the Purchaser's country for the amount payable in the currency of the Purchaser's country.

31.2 The currency selected for converting bid prices to a common base for the purpose of evaluation, along with the source and date of the exchange rate, are specified in the **Bid Data Sheet.**

**32. Evaluation and Comparison of Bids**

32.1 The Purchaser will evaluate and compare the bids that have been determined to be substantially responsive, pursuant to ITB Clause 29.

32.2 The Purchaser's evaluation and comparison of a bid will be based on the total cost at destination including all taxes and duties paid or to be payable if contract is awarded.

32.3 The comparison shall be between net landed prices at final destination.

32.4 The Purchaser's evaluation of a bid will take into account, in addition to the bid price quoted in accordance with ITB Sub-Clause 16.2, one or more of the following factors as specified in the BDS, and quantified in ITB Sub-Clause 32.5*:*

(a) delivery schedule offered in the bid;

(b) deviations in payment schedule from that specified in the Special Conditions of Contract;

(c) other specific criteria indicated in the **Bid Data Sheet** and/or in the Technical Specifications.

32.5 For factors retained in the **Bid Data Sheet** pursuant to ITB Sub-Clause 32.4, one or more of the following quantification methods will be applied, as detailed in the **Bid Data Sheet:**

(a) Delivery schedule.

The Purchaser requires that the Health Sector Goods under these Bidding Documents shall be delivered (shipped) at the time specified in

the Schedule of Requirements. The estimated time of arrival of the Health Sector Goods at the site will be calculated for each bid after allowing for reasonable international and inland transportation time. A delivery "adjustment" will be calculated for and added to each bid by applying a percentage, specified in the **Bid Data Sheet,** of the EXW/CIF/CIP price for each week of delay beyond the expected time of arrival specified in the Bidding Documents for evaluation purposes. No credit shall be given to early delivery.

(b) Deviation in payment schedule.

Bidders shall state their bid price for the payment schedule outlined in the SCC. Bids will be evaluated on the basis of this base price. Bidders are, however, permitted to state an alternative payment schedule and indicate the reduction in bid price they wish to offer for such alternative payment schedule. The Purchaser may consider the alternative payment schedule offered by the selected Bidder.

(c) Other specific additional criteria to be considered in the evaluation and the evaluation method shall be detailed in the **Bid Data Sheet** and/or in the Technical Specifications.

**33. Domestic Preference**

33.1 If indicated in the **Bid Data Sheet** and for the purpose of bid comparison, the Purchaser will grant a margin of preference to Goods manufactured in the Purchaser's country. This margin of preference will be granted in accordance with the procedures outlined in subsequent paragraphs, provided the Bidder shall have established to the satisfaction of the Purchaser and of the Bank that its bid complies with the criteria specified in ITB Paragraph 15.2 (a).

33.2 The Purchaser will first review the bids to confirm the appropriateness of, and to modify if necessary, the bid group classification to which Bidders assigned their bids in preparing their Bid Forms and Price Schedules.

33.3 All evaluated bids in each group will then be compared among themselves to determine the lowest evaluated bid of each group. The lowest evaluated bid of each group will next be compared with the lowest evaluated bids of the other groups. If this comparison results in a bid from Group A or Group B being the lowest, it will be selected for Contract award.

33.4 If, as a result of the preceding comparison, the lowest evaluated bid is from Group C, all Group C bids will then be further compared with the lowest evaluated bid from Group A, after adding to the evaluated bid price of the imported Goods offered in each Group C bid, for the purpose of this further comparison only, a flat rate of

fifteen (15) percent of the CIF (or CIP border point or CIP named place of destination, as the case may be) bid price of such Goods.

Domestic preference will be applied only to those items indicated in the Schedule of Requirements that meet the criteria under Paragraph 15.2 (a).

If the Group A bid in the further comparison is the lowest, it will be selected for award. If not, the lowest evaluated bid from Group C, as determined from the comparison under ITB Sub-Clause 33.3 above, will be selected for award.

## F. AWARD OF CONTRACT

**34. Post-qualification**

34.1 In the absence of prequalification, the Purchaser will determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITB Sub-Clause 7.1 and any additional post-qualification criteria stated in the **Bid Data Sheet.** If a prequalification process was undertaken for the Contract(s) for which these Bidding Documents were issued, the Purchaser will determine in the manner described above that no material changes have occurred after the prequalification that negatively affect the ability of the Bidder that has submitted the lowest evaluated bid to perform the Contract.

34.2 The determination will evaluate the Bidder's financial, technical, and production capabilities. It will be based on an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Sub-Clause 7.1, as well as other information the Purchaser deems necessary and appropriate.

34.3 An affirmative post qualification determination will be a prerequisite for award of the contract to the lowest evaluated Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Purchaser will proceed to the next-lowest evaluated Bidder to make a similar determination of that Bidder's capabilities to perform satisfactorily.

**35. Award Criteria**

35.1 Pursuant to ITB Clauses 32, 33, and 38, the Purchaser will award the Contract to the Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily, pursuant to ITB Clause 34.

**36. Purchaser's Right to Accept Any Bid and to Reject Any or All Bids**

36.1 The Purchaser reserves the right to accept or reject any bid, or to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to the affected Bidder or Bidders.

**37. Purchaser's Right to Vary Quantities at Time of Award**

37.1 The Purchaser reserves the right at the time of Contract award to increase or decrease, by the percentage indicated in the **Bid Data Sheet,** the quantity of goods and services beyond that originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions.

**38. Notification of Award**

38.1 Prior to the expiration of the period of bid validity, the Purchaser will notify the successful Bidder in writing by registered letter or by cable, to be subsequently confirmed in writing by registered letter, that its bid has been accepted.

38.2 The notification of award will constitute the formation of the Contract.

38.3 Upon the successful Bidder's furnishing of the signed Contract Form and performance security pursuant to ITB Clause 40, the Purchaser will promptly notify each unsuccessful Bidder and will discharge its bid security,

pursuant to ITB Clause 19.

38.4 If, after notification of award, a Bidder wishes to ascertain the grounds on which its bid was not selected, it should address its request to the Purchaser. The Purchaser will promptly respond in writing to the unsuccessful Bidder.

38.5 The Purchaser shall publish in the NACO's and SAMS'S website the results identifying the bid and lot numbers and the following information: (i) name of each Bidder who submitted a Bid; (ii) bid prices as read out at bid opening; (iii) name and evaluated prices of each Bid that was evaluated; (iv) name of bidders whose bids were rejected and the reasons for their rejection; and (v) name of the winning Bidder, and the price it offered, as well as the duration and summary scope of the contract awarded. After publication of the award, unsuccessful bidders may request in writing to the Purchaser for a debriefing seeking explanations on the grounds on which their bids were not selected. The Purchaser shall promptly respond in writing to any unsuccessful Bidder who, after Publication of contract award, requests a debriefing.

**39. Signing of Contract**

39.1 Promptly after the Purchaser notifies the successful Bidder that its bid has been accepted, the Purchaser will send the Bidder the Contract Form provided in the Bidding Documents, incorporating all agreements between the parties.

39.2 Within twenty-eight (28) days of receipt of the Contract Form, the successful Bidder shall sign and date the Contract Form and return it to the Purchaser.

**40. Performance Security**

40.1 Within twenty-eight (28) days of the receipt of notification of award from the Purchaser, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, using the Performance Security Form provided in the Bidding Document, or in another form acceptable to the Purchaser.

40.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 39 or ITB Sub-Clause 40.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Purchaser may make the award to the next-

lowest evaluated bid submitted by a qualified Bidder or call for new bids.

# SECTION - II

# BID DATA SHEET

# Bid Data Sheet

The following specific data for the Goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions in the Bid Data Sheet (BDS) shall prevail over those in the ITB.

## A. GENERAL

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| ITB 1.1 | **Name of Purchaser**:<br><br>**National AIDS Control Organization (NACO),**<br>Ministry of Health & Family Welfare (Govt. of India)<br>6th & 9th Floor, Chanderlok Building,<br>36, Janpath, New Delhi 110001<br><br>**Name of Authorized Procurement Agent**:<br><br>**Strategic Alliance Management Services Pvt. Ltd. (SAMS),**<br>1/ 1B, Choudhary Hetram House, Bharat Nagar,<br>New Friends Colony, New Delhi 110025, INDIA<br>**Phones:** 8800257774, 9958994797, 011-41653612<br>**Email:** pronaco@samsconsult.com<br><br>SAMS will be handling the bidding process as well as sign the contracts for this IFB on behalf of the Purchaser. The Purchaser will exercise all rights and obligations through SAMS for the purpose of this tender.<br><br>Type of Goods: **Methadone Syrup with Dispensing Bottles**<br><br>Name and identification number of the Contract:<br><br>**Procurement of Methadone Syrup**<br><br>**IFB NO.:- SAMS/NACP/Methadone/05/2015** |
| ITB 2.1 | Name of the Borrower: **Ministry of Health & Family Welfare (Govt. of India)**<br>Name of Project: **National AIDS Control Support Project (NACSP)**<br><br>Source of funding**:** **The World Bank.** |
| ITB 4.1 & 5.1 | Applicable edition of the ***Guidelines: Procurement under IBRD Loans and IDA Credits*****:** ***January, 2011 Edition and revised July, 2014*** |

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| ITB 4.3 | The list of such ineligible firms is available on the website of World Bank " http://www.worldbank.org/debarr" |
| ITB 6.3 (c) | Documentation requirements for eligibility of Goods. In addition to the documents stated in Clause 6.2 and 6.3 (a) and (b), the following documents should be included with the Bid:<br><br>The Goods offered should meet the specified pharmaceuticals standards as stated in the Technical Specification. If the Goods offered are not included in one of the specified pharmacopoeias (e.g., the case of new drug), the Bidder will provide testing protocols and alternative standards. |
| ITB 6.4 | The Applicable Law requires registration of the imported goods to be supplied under the contract, with relevant authorities in India. |
| ITB 6.4 (b) | By the time of Contract signing, the successful Bidder shall have to submit the following documentary evidence:<br><br>1) Copy of Registration Certificate establishing registration of Goods to be supplied under the Contract, with the National Regulatory Authority of India viz. Central Drugs Standard Control Organization (CDSCO).<br><br>2) Copy of documentation indicating that the goods proposed to be supplied under this contract are registered and licensed for use in India by the DCG (I) (Drugs Controller General of India) for imported pharmaceuticals and by the competent authority defined under the Drugs and Cosmetics Act 1940, as amended, after appropriate evaluation by centers approved by the DCG (I) (Drugs Controller General of India) for pharmaceuticals produced by indigenous manufacturers.<br><br>**Note**: Bidders are requested to inquire in advance about the registration requirements and procedures in order to avoid any delays due to involvement of various government agencies. Purchaser shall not be responsible for any delay on this account / grant any delivery extension/ extend any help in getting the same. |
| ITB 6.4.1 | Additional information about the requirements for registration can be obtained from the Website: www.cdsco.nic.in |
| ITB 7.1 (a) | **Qualification requirements for Bidders are listed below:**<br><br>Along with the bid, the Bidder should submit documentary evidence on its qualification to perform the Contract if its bid is |

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| | accepted as detailed below:<br><br>**(A) Manufacturer Bidder**<br><br>(i) Provides the evidence that it has the financial, technical and production capability necessary to perform the contract as under:<br><br>1. That it has successfully completed at least **one (1) similar contract** within the period of **last five years** (preceding two months before the date of bid opening) for supply of drugs. Value of completed contract should be as per Appendix 'A' and that include comparable products. Bidder shall submit list of major supply contracts conducted within the last five years as per form 11 in Section VIII.<br><br>2. That it has achieved an actual annual production of, specific or similar goods specified in Schedule of requirement of at least **1/3rd** quantities specified in "Section VI Schedule of requirements" during any one year of the last **three (3), financial years**; certified by chartered accountant and supported by **audited Annual Report**.<br><br>3. That it has generated an annual turnover of at least of the value as given in Appendix 'B', in any of the last three financial years, to qualify. The turnover is to be supported by **audited financial statements** of accounts (including balance sheet, profit and loss account, auditor's reports, and IT returns) for the past **three financial years** duly certified by the auditor of the Company.<br><br>4 Provides proof of experience with and knowledge of modes of packing, distribution, and transportation of drugs/goods similar to those specified within bidding document subject to under logistical and climatic conditions similar to the ones in the purchaser's country. It should provide names of clients/countries to which the bidder has supplied (including packaged, distributed, and transported) products worth at least equivalent to US $ 10,000 or more within the past five financial years. |

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| | The following documents must be included with the bid:<br><br>Documentary evidence of the Bidder's qualifications to perform the contract if its bid is accepted:<br><br>(ii) that, in the case of a Bidder offering to supply Goods under the Contract which the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder:<br><br>(a) is incorporated in the country of manufacture of the Goods;<br><br>(b) has been licensed by the regulatory authority in the country of manufacture to supply the Goods covered by the IFB;<br><br>(c) has manufactured and marketed the specific good covered by the bidding document for at least **One (1) year**, and for **similar goods** for at least **three (3) years.** In support of this, data on past performance should be submitted as per Form 11 in Section VIII.<br><br>Experience of manufacturing and marketing in any strength shall be considered as having experience of manufacturing and marketing goods in other strengths also.<br><br>(d) has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on Pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the goods [for the factory where the specific pharmaceuticals are manufactured and are being offered for supply] or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the above said quality standards during the past one (1) year prior to bid submission.<br><br>Note: WHO GMP should be valid on the date of bid opening.<br><br>(e) Has a valid certificate of pharmaceuticals product (COPP) as recommended by the WHO for product offered. COPP should be valid on the date of bid opening. |

(iii) The Bidder shall also submit the following additional information:

a) Details of on-site quality control laboratory facilities and services and range of tests conducted should be submitted. The manufacturer should have a Quality Management System to the satisfaction of the purchaser.

b) Capacity and quality certification form in the specified format (Form 12 of Section VIII).

**(B) Non Manufacturer Bidder**

a) In the case of a Bidder offering to supply Goods under the Contract that the Bidder does not manufacture or otherwise produce **the Bidder should be duly authorized by the manufacturer of the Goods who meets the criteria under (A) above** (all supporting documents/information as asked above for manufacturer shall be submitted with the bid) for the respective items supplied by such manufacturer(s), as per authorization Form- 8 in Section VIII;

b) The bidder has successfully completed **at least one similar contract** within the period of last five years (preceding two months before the date of opening of bids) for supply of goods against the schedule offered. Value of completed contract should be at least 50% of the value to that indicated in Appendix A and that includes comparable products e.g. Tablets. The bidder will also submit the list of major supply contracts completed within the last five years as per Form 11 in Section VIII.

c) that it has generated an annual turnover of at least 50% of the value as given in Appendix ‘B’, in any of the last three financial years, to qualify for the product. The turnover is to be supported by audited financial statements of accounts (including balance sheet, profit and loss account, auditor’s reports, and IT returns) for the past three financial years duly certified by the auditor of the Company.

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| | **For Both (A) and (B)**<br>I. Copies of original documents defining the constitution or legal status, place of registration, and principal place of business;<br>II. **written power of attorney** of the signatory of the Bid to commit the Bidder;<br>III. List of major supply contracts completed within the last five years as per Form 11 in Section VIII.<br>IV. A copy of the achieved annual production rate certified by Chartered Accountant.<br>V. Copies of its **audited Annual Report** & financial statements (including balance sheet, profit and loss account, auditor's reports, and IT returns) for the past three financial years.<br>VI. List of major supply contracts conducted (Completed & ongoing) with in last five years as per form 11 in Section VIII.<br>VII. The bidder and the manufacturer whose product is offered by the bidder shall disclose instance of previous past performance of his and the manufacturer whose product is procured by the bidder, that may have resulted into adverse actions taken against the bidder during the last two years. Such adverse actions taken against the bidder or manufacturer may be treated as unsatisfactory performance history while deciding the award of contract. If no adverse action has been taken against the Bidder, the Bidder must provide a statement in its bid saying that there has been no such previous past performance resulting in adverse actions being taken against him.<br>VIII. The bidder shall provide an undertaking that:<br>(a) The proprietor/promoter/director of the firm, its employee, partner or representative is not convicted by a court of law following prosecution for offence involving moral turpitude in relation to business dealings including malpractices such as bribery, corruption, fraud, substitution of bids, interpolation, misrepresentation, evasion, or habitual default in payment of tax levied by law; etc. |

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(b) The firm does not employ a government servant, who has been dismissed or removed on account of corruption.<br><br>
IX. List of drugs being manufactured by the bidder with product registration/ license number and date.<br><br>
Note:<br><br>
(a) An agent submitting a bid in its own name will be treated as a non-manufacturer bidder.<br><br>
(b) The bidder must complete the check list given in Form 22 in Section VIII and submit it along with the Bid. It is essential that Bidders review carefully this Checklist to ensure that their Bid is complete and includes all required information.<br><br>
(c) The bidder should Serial no. all the documents of his bid, provide a summary table & sign/initial all the pages.<br><br>
(d) Details of two persons (other than authorized signatory) that SAMS may contact for requests for clarification during bid evaluation:<br><br>
<table>
<tr><td>Name</td><td></td><td></td></tr>
<tr><td>Designation</td><td></td><td></td></tr>
<tr><td>Telephone No (direct)</td><td></td><td></td></tr>
<tr><td>Email address</td><td></td><td></td></tr>
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<br>
(e) The Bank details from where the Bank Guarantee has been issued along with Phone, fax numbers and email Ids. For Banks from outside India the details of the correspondent Bank in India.
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<td>ITB 7.1 (d)</td>
<td>The bidder must meet the qualification criteria as listed in the Bid Data Sheet. as above in 7.1 (a)</td>
</tr>
</table>

## B. THE BIDDING DOCUMENTS

| | |
|---|---|
| ITB 11.1 | Purchaser's duly authorized Procurement Agent's address:<br><br>Strategic Alliance Management Services Pvt. Ltd. (SAMS),<br>1/ 1B, Choudhary Hetram House, Bharat Nagar,<br>New Friends Colony, New Delhi 110025, INDIA<br>Phones: 8800257774, 9958994797, 011-41653612<br>Email: pronaco@samsconsult.com |

## C. PREPARATION OF BIDS

| | |
|---|---|
| ITB 13.1 | The language of all correspondence and documents related to the bid is: ***English***. Moreover, the key passages of all accompanying printed literature in any other language must be translated into the above language with due authentication. |
| ITB 14.1 (h) | In addition to the documents stated in Paragraphs 14.1 (a) through (g), the following documents must be included with the Bid:<br><br>➢ Certificate of incorporation of the manufacturer<br><br>➢ The bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer is licensed to manufacture the Goods offered.<br><br>The following details shall also be provided by Indian Bidders:<br><br>a) Name, address, PAN and Income Tax details(ward/circle where they are being assessed) of the Directors of the Bidding Company.<br><br>b) Company's PAN and Income Tax details and ward/circle where it is being assessed (authenticated photocopies to be attached),<br><br>c) Registration details of the company under VAT, local and Central Sales Tax, and other laws as may be applicable (authenticated photocopies to be attached). |
| ITB 15.2 & 15.3 | Deleted |

| | |
|---|---|
| ITB 16.2 (a) (i) | Insert the words "Excise and other" in between the words "customs" and "duties" in lines 3 and 4 of this Sub-Clause |
| ITB 16.2 (a) (ii) | Insert the word ", or VAT" after word "Sales Tax" in line 1. |
| ITB 16.2 ( a) (iii) & (c) (v) | "The final destination is specified in Schedule of Requirements (Section VI) |
| 16.2 (a) (iv) | Insert the following as Clause 16.2 (a) ( iv)<br>The incidental services to be provided are specified in clause 14 of the special conditions of contract. |
| ITB 16.2 (c) (iii) | Prices of goods offered shall be quoted as **CIP final place of destination** mentioned in the schedule of requirement. |
| ITB 16.2 (b) (ii) & (iii) | Deleted |
| ITB 16.5 | Prices quoted by the Bidder shall be ***"fixed".*** |
| ITB 17 | Deleted |
| ITB 18.1 | Bids shall remain valid up to 21st June 2016. A bid valid for a shorter period shall be rejected by the purchaser as non-responsive**.** |
| ITB 18.3 | Substitute this clause with the following"<br>"In the case of fixed price contracts, if the award is delayed by a period exceeding fifty-six (56) days beyond the expiry of the first bid validity extension and in the event that the Purchaser requests and the Bidder agrees to an extension of the validity period, the contract prices, if the bidder is selected for award, shall be the bid price corrected as follows :<br>the price shall be increased by the factor **(5% per annum**) to be calculated per week, or part of a week, that has elapsed from the expiration of the initial bid validity to the date of notification of award of the successful Bidder. |
| ITB 18.4 | Insert the following as Clause 18.4:<br>Bid evaluation will be based on the bid prices without taking into consideration the correction indicated in clause 18.3 above. |
| ITB 19.1 | The amount of bid security should be in fixed amount as specified in the Schedule of Requirements. |
| ITB 19.2 | Replace the clause with the following:<br>"The bid security shall remain valid for a period of 28 days beyond the validity period for the bid i.e. up to, and beyond any extension subsequently requested under Sub-clause 18.2." |

| | |
|---|---|
| ITB 19.3 | The bid security shall be denominated in the Indian currency i.e. Indian Rupees and shall on the bidder's option, be in the form of either a pay order, a demand draft or a bank guarantee from nationalized/scheduled bank in favour of Strategic Alliance Management Services Pvt. Ltd." Payable at Delhi<br><br>**The bank guarantee shall be issued either by a Bank located in the country of the Purchaser (Nationalized or Scheduled Bank in India) or a foreign Bank through a correspondent bank located in the country of the Purchaser (Nationalized or Scheduled Bank in India)**, acceptable to the purchaser. |
| ITB 19.8 | Deleted |
| ITB 20.1 | Alternative bids **will not** be accepted. The bidder should not submit more than one bid for any Schedule. |
| ITB 21.1 | Required number of copies of the bid: 02 (One original + One copy). In addition scanned bid copied in CD/Pen-drive also must be submitted. |

## D. SUBMISSION OF BIDS

| | |
|---|---|
| ITB 22.1 (b) | Bidders shall not have the option of submitting their bids electronically. |
| ITB 22.2 (b) | The Bid will be addressed to :-<br><br>Strategic Alliance Management Services Pvt. Ltd. (SAMS),<br>1/ 1B, Choudhary Hetram House, Bharat Nagar,<br>New Friends Colony, New Delhi 110025, INDIA<br>Phones: 8800257774, 9958994797, 011-41653612 |
| ITB 22.2 (c) & (d) | The inner and outer envelopes shall bear the following additional identification marks:<br>Invitation for Bids Title :<br>Invitation for Bids Number:<br>Time & Date of Submission of Bids:<br>Name of the Goods |
| ITB 23.1 | The address for bid submission is as per ITB 22.2(b)<br><br>Deadline for bid submission shall be as indicated in the notification.<br><br>Add the following new sentence at the end of Sub-Clause |

| | |
|---|---|
| | 23.1:<br>"In event of the specified date for the submission of Bids being declared a holiday for the Purchaser, the Bids will be received up to the appointed time on the next working day". |
| ITB 24.1 | See the above data for ITB Sub-Clause 23.1 for the deadline for bid submission. |
| ITB 25.1 | Insert the following words as the first sentence in Sub-clause 25.1:<br>"No bid may be modified subsequent to the deadline for submission of bids." |
| ITB 25.2 (a) | The required number of copies of bid modifications is the same as the number of copies of the original bid specified above in the data for ITB Sub-Clause 21.1. |
| ITB 25.3 (a) | See the above data for ITB Paragraph 22.2 (b) for the address to use for submission of a bid withdrawal notice. |

## E. BID OPENING AND EVALUATION

| | |
|---|---|
| ITB 26.1 | Time, date, and place for bid opening shall be as indicated in the notification.<br><br>Add at the end of this clause:<br><br>"In the event of the specified date of the bid opening being declared a holiday for the Purchaser, the bids shall be opened at the appointed time and location on the next working day." |
| ITB 29.3 | The following clauses are the critical provisions deviations from or objections or reservations to which, will be treated as material deviations:<br>- Non submission of Bid Form<br>- Bid Validity (ITB Clause 18)<br>- Bid Security (ITB Clause 19);<br>- Validity of Bid Security ( ITB Clause 19.2 )<br>- Performance Security (GCC Clause 8);<br>- Delivery Terms (GCC Clause 11 & Schedule of Requirements)<br>- Warranty (GCC Clause 15);<br>- Payment terms (GCC Clause 16)<br>- Force Majeure (GCC Clause 24);<br>- Limitation of liability (GCC Clause 28)<br>- Applicable Law (GCC Clause 30); |

| | |
|---|---|
| | - Taxes and Duties (GCC Clause 32);<br>- Technical Specification (As per Section VII)<br>- Delivery Period (Schedule of Requirements)<br><br>Above list is non-exhaustive. |
| ITB 29.4 | Replace the second sentence with the following:<br><br>"The Purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence." |
| ITB 31. 1 to 33.4 | Deleted. |
| ITB 32.1 | The purchaser will evaluate and compare the bids previously determined to be substantially responsive, pursuant to ITB clause 29. No bid will be considered if the complete requirements covered in the schedule is not included in the bid. |
| ITB 32.4 (c) | No other specific criteria |
| ITB 32.5 | No other factor will be applicable |
| ITB 32.5 (a) | Deviations in the delivery schedule are not permitted. |
| ITB 32.5 (b) | Deviations in the payment schedule are not permitted. |
| ITB 33.1 | A margin of domestic preference **will apply** as indicated in clause 33.4. |

## a. POST QUALIFICATION AND AWARD OF CONTRACT

| | |
|---|---|
| ITB 34.1 | Before the award of the contract the purchaser may inspect the manufacturing facilities of the responsive bidders or manufacturers of the Goods to assess their capacity to successfully perform the contract as per the terms and conditions specified in the bid document. |
| ITB 37.1 | The clause is modifies as below:<br><br>The Purchaser has the right to increase or decrease the quantities required by 25% at the time of award of contract. |

## APPENDIX 'A'

| Item No. | Minimum value of completed contract (In Rupees Lakh) | Similar Product |
|---|---|---|
| I & II | 5.00 | Syrup |

# APPENDIX 'B'

| Item No. | Annual Turnover (in Rupees Lakhs) |
|---|---|
| I & II | 60.00 |

# SECTION - III

# ELIGIBLE COUNTRIES

# Section III. Eligible Countries

## Eligibility for the Provision of Goods, Works and Services in Bank-Financed Procurement

a) In accordance with Para 1.8 of the Guidelines: Procurement under IBRD Loans and IDA Credits, dated May 2004, Revised January 2011, the Bank permits firms and individuals from all countries to offer goods, works and services for Bank-financed projects. As an exception, firms of a Country or goods manufactured in a Country may be excluded if:

Para 1.8 (a) (i): as a matter of law or official regulation, the Borrower's Country prohibits commercial relations with that Country, provided that the Bank is satisfied that such exclusion does not preclude effective competition for the supply of the Goods or Works required, or

Para 1.8 (a) (ii): by an Act of Compliance with a Decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Borrower's Country prohibits any import of goods from that Country or any payments to persons or entities in that Country.

b) For the information of borrowers and bidders, at the present time firms, goods and services from the following countries are excluded from this bidding:

**1** With reference to paragraph 1.8 (a) (i) of the Guidelines: **Nil**

**2** With reference to paragraph 1.8 (a) (ii) of the Guidelines: **Nil**

# SECTION-IV

# GENERAL CONDITIONS OF CONTRACT (GCC)

# TABLE OF CLAUSES

# General Conditions of Contract

**1. Definitions**

1.1 In this Contract, the following terms shall be interpreted as indicated:

(a) "The Contract" means the agreement entered into between the Purchaser and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

(b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.

(c) "Day" means calendar day.

(d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Clause 6.2.

(e) "Eligible Country" means the countries and territories eligible for participation in procurements financed by the World Bank as defined in the *Guidelines: Procurement under IBRD Loans and IDA Credits*.

(f) "End User" means the organization(s) where the goods will be used, as **named in the SCC.**

(g) "GCC" means the General Conditions of Contract contained in this section.

(h) "The Goods" means all of the pharmaceuticals including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms that the Supplier is required to supply to the Purchaser under the Contract.

(i) "The Purchaser" means the organization purchasing the Goods, as **named in the SCC.**

(j) "The Purchaser's country" is the country **named in the SCC.**

(k) "Registration Certificate" means the certificate of registration or other documents in lieu thereof

establishing that the Goods supplied under the Contract are registered for use in the Purchaser's country in accordance with the Applicable Law.

(l) "SCC" means the Special Conditions of Contract.

(m) "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.

(n) "The Site," where applicable, means the place or places **named in the SCC.**

(o) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract, as **named in the SCC.**

(p) "The World Bank" means the International Bank for Reconstruction and Development (IBRD) or the International Development Association (IDA).

**2. Application**

2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

**3. Country of Origin**

3.1 All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules of the World Bank, as further **elaborated in the SCC.**

3.2 For purposes of this Clause, "origin" means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.

**4. Standards**

4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications and, when no applicable standard is

mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

**5. Use of Contract Documents and Information; Inspection and Audit by the Bank**

5.1 The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Sub-Clause 5.1 except for purposes of performing the Contract.

5.3 Any document, other than the Contract itself, enumerated in GCC Sub-Clause 5.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.

5.4 The Supplier shall permit the Bank and/or persons appointed by the Bank to inspect the Supplier's offices and/or the accounts and records of the Supplier and its sub-contractors relating to the performance of the Contract, and to have such accounts and records audited by auditors appointed by the Bank if required by the Bank. The Supplier's attention is drawn to Clause 23, which provides, inter alia, that acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under this Sub-Clause constitute a prohibited practice subject to contract termination (as well as to a determination of ineligibility under the Procurement Guidelines).

**6. Certification of Goods in Accordance with Laws of the Purchaser's Country**

6.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in the Purchaser's country. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in the Purchaser's country.

6.2 Unless otherwise **specified in the SCC,** the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the Purchaser's country that the Goods have been registered for use in the Purchaser's country.

6.3 If thirty (30) days, or such longer period **specified in the SCC,** elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 6.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's performance security shall be promptly returned.

**7. Patent Rights**

7.1 The Supplier shall indemnify the Purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in the Purchaser's country.

**8. Performance Security**

8.1 Within twenty-eight (28) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Purchaser the performance security in the amount **specified in the SCC.**

8.2 The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

8.3 The performance security shall be denominated in the currency of the Contract, or in a freely convertible currency acceptable to the Purchaser, and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Purchaser's country or abroad, acceptable to the Purchaser, in the format provided in the Bidding Documents or another format acceptable to the Purchaser; or

(b) a cashier's or certified check.

8.4 The performance security will be discharged by the Purchaser and returned to the Supplier not later than thirty (30) days following the date of completion of the

Supplier's performance obligations under the Contract, including any warranty obligations, unless **specified otherwise in the SCC.**

**9. Inspections and Tests**

9.1 The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications. The **SCC** and the Technical Specifications shall specify what inspections and tests the Purchaser requires and where they are to be conducted. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

(a) Said inspection and testing is for the Purchaser's account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.

(b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

(c) Upon receipt of the Goods at place of final destination, the Purchaser's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within ten (10) days of receipt of the Goods or part of Goods at place of final destination.

9.2 Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 9.1 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and

binding on both parties. The cost of umpire analysis will be borne by the losing party.

**10. Packing**

10.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.

10.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, **specified in the SCC** or Technical Specifications, and in any subsequent instructions ordered by the Purchaser.

**11. Delivery and Documents**

11.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are **specified in the SCC.**

11.2 For purposes of the Contract, "EXW," "FOB," "FCA," "CIF," "CIP," and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of *Incoterms* published by the International Chamber of Commerce, Paris.

11.3 Documents to be submitted by the Supplier are **specified in the SCC.** *Incoterms* provides a set of international rules for the interpretation of the more commonly used trade terms.

**12. Insurance**

12.1 The Goods supplied under the Contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery in the manner **specified in the SCC.**

12.2 Where delivery of the Goods is required by the

Purchaser on a CIF or CIP basis, the Supplier shall arrange and pay for cargo insurance, naming the Purchaser as beneficiary. Where delivery is on an FOB or FCA basis, insurance shall be the responsibility of the Purchaser.

**13. Transportation**

13.1 Where the Supplier is required under Contract to deliver the Goods FOB, transport of the Goods, up to and including the point of putting the Goods on board the vessel at the specified port of loading, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price. Where the Supplier is required under the Contract to deliver the Goods FCA, transport of the Goods and delivery into the custody of the carrier at the place named by the Purchaser or other agreed point shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

13.2 Where the Supplier is required under Contract to deliver the Goods CIF or CIP, transport of the Goods to the port of destination or such other named place of destination in the Purchaser's country, as shall be specified in the Contract, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

13.3 Where the Supplier is required under the Contact to transport the Goods to a specified place of destination within the Purchaser's country, defined as the Site, transport to such place of destination in the Purchaser's country, including insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.

13.4 Where the Supplier is required under Contract to deliver the Goods CIF or CIP, no restriction shall be placed on the choice of carrier. Where the Supplier is required under Contract (a) to deliver the Goods FOB or FCA, and (b) to arrange on behalf and at the expense of the Purchaser for international transportation on specified carriers or on national flag carriers of the Purchaser's country, the Supplier may arrange for such transportation on alternative carriers if the specified or national flag carriers are not available to transport the Goods within the period(s) specified in the Contract.

**14. Incidental Services**

14.1 The Supplier shall provide such incidental services, if any, as are **specified in the SCC.**

14.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.

**15. Warranty**

15.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/airport of entry for goods with a shelf life of more than two years and three-fourths (3/4) for goods with a shelf life of two years or less, unless otherwise **specified in the SCC;** have “overages” within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

15.2 The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.

15.3 In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer’s retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.

15.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period **specified in the SCC,** the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

15.5 *Recalls.* In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.

**16. Payment**

16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be **specified in the SCC.**

16.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 11, and upon fulfillment of other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Purchaser, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.

16.4 The currency or currencies in which payment is made to the Supplier under this Contract shall be **specified in the SCC** subject to the following general principle: Payment will be made in the currency or currencies in which the payment has been requested in the Supplier's bid.

16.5 All payments shall be made in the currency or

currencies specified in the SCC pursuant to GCC 16.4.

**17. Prices**

17.1 Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid, with the exception of any price adjustments **authorized in the SCC** or in the Purchaser's request for bid validity extension, as the case may be.

**18. Change Orders**

18.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:

(a) specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;

(b) the method of shipment or packing;

(c) the place of delivery; and/or

(d) the Services to be provided by the Supplier.

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Purchaser's change order.

**19. Contract Amendments**

19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

**20. Assignment**

20.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Purchaser's prior written consent.

**21. Delays in the Supplier's Performance**

21.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.

21.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly

notify the Purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.

21.3 Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of liquidated damages.

**22. Liquidated Damages**

22.1 Subject to GCC Clause 24, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage **specified in the SCC** of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage **specified in the SCC.** Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 23.

**23. Termination for Default**

23.1 The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:

(a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 21; or

(b) if the Goods do not meet the Technical Specifications stated in the Contract; or

(c) if the Supplier fails to provide any registration or other certificates in respect of the Goods within the time specified in the Special Conditions.

(d) if the Purchaser determines that the Supplier has

engaged in corrupt, fraudulent, collusive, coercive or obstructive practices, in competing for or in executing the Contract, then the Purchaser may, after giving 14 days notice to the Supplier, terminate the Supplier's employment under the Contract and cancel the contract, and the provisions of Clause 23 shall apply as if such expulsion had been made under Sub-Clause 23.1.

For the purposes of this Sub-Clause:

(i) "corrupt practice"[6] is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(ii) "fraudulent practice"[7] is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii) "collusive practice"[8] is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

(iv) "coercive practice"[9] is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(v) "obstructive practice" is

(aa) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in

[6] "Another party" refers to a public official acting in relation to the procurement process or contract execution]. In this context, "public official" includes World Bank staff and employees of other organizations taking or reviewing procurement decisions.

[7] A "party" refers to a public official; the terms "benefit" and "obligation" relate to the procurement process or contract execution; and the "act or omission" is intended to influence the procurement process or contract execution.

[8] "Parties" refers to participants in the procurement process (including public officials) attempting to establish bid prices at artificial, non competitive levels.

[9] A "party" refers to a participant in the procurement process or contract execution.

order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(bb) acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under Clause 5.

(e) should any employee of the Supplier be determined to have engaged in corrupt, fraudulent, collusive, coercive, or obstructive practice during the purchase of the Goods, then that employee shall be removed.

(f) if the Supplier fails to perform any other obligation(s) under the Contract.

23.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 23.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

**24. Force Majeure**

24.1 Notwithstanding the provisions of GCC Clauses 21, 22, and 23, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

24.2 For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine

restrictions, and freight embargoes.

24.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

**25. Termination for Insolvency**

25.1 The Purchaser may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser.

**26. Termination for Convenience**

26.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

26.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect:

(a) to have any portion completed and delivered at the Contract terms and prices; and/or

(b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.

**27. Settlement of Disputes**

27.1 If any dispute or difference of any kind whatsoever shall arise between the Purchaser and the Supplier in connection with or arising out of the Contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to

resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given.

27.2.1 Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.

27.2.2 Arbitration proceedings shall be conducted in accordance with the rules of procedure **specified in the SCC.**

27.3 Notwithstanding any reference to arbitration herein,

(a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and

(b) the Purchaser shall pay the Supplier any monies due the Supplier.

**28. Limitation of Liability**

28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 7,

(a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser and

(b) the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

**29. Governing Language**

29.1 The Contract shall be written in the language **specified in the SCC.** Subject to GCC Clause 30, the version of the Contract written in the specified language shall

govern its interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.

**30. Applicable Law**

30.1 The Contract shall be interpreted in accordance with the laws of the Purchaser's country, unless otherwise **specified in the SCC.**

**31. Notices**

31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex, or facsimile and confirmed in writing to the other party's address **specified in the SCC.**

31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

**32. Taxes and Duties**

32.1 A Supplier supplying Goods from abroad shall be entirely responsible for all taxes, stamp, duties, license fees, and other such levies imposed outside the Purchaser's country.

32.2 A Supplier supplying Goods offered locally shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Purchaser.

# SECTION -V

# SPECIAL CONDITIONS OF CONTRACT (SCC)

# Special Conditions of Contract (SCC)

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| The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated below: | |
| GCC 1.1 (d) | Effective Date of the Contract is the date of Notification of Award. |
| GCC 1.1 (f) | The End User is the consignees stated in the schedule of requirements. |
| GCC 1.1 (i) | The Purchaser is*:* Ministry of Health & Family Welfare, National AIDS Control Organization (NACO), Government of India.<br><br>Strategic Alliance Management Services Pvt. Ltd. (SAMS) is the authorized Procurement Agent of the Purchaser and the Purchaser will exercise all rights and obligation under this contract through the Procurement Agent pursuant to the Agreement between the Ministry of Health and Family Welfare (MOHFW), Government of India and SAMS. |
| GCC 1.1 (j) | The Purchaser's country is: India. |
| GCC 1.1 (n) | The final Destination Sites are: As specified in the Schedule of Requirement. |
| GCC 1.1 (o) | The Supplier is: as mentioned in Notification of Award |
| GCC 3.1 | The Bank maintains a list of countries whose Bidders for Goods and Services are not eligible to participate in procurement financed by the Bank. This list is updated regularly, and it is available from the Public Information Center of the World Bank. A copy of this list is contained in the section of the Bidding Documents entitled "Eligibility for the Provisions of Goods, Works, and Services in Bank-Financed Procurement." |
| GCC 6.1 | The Supplier or its manufacturer/s of the Goods to be supplied under this Contract must have a valid Manufacturing license from the Regulatory Authority of the country of manufacture/registration with CDSCO (Central Drug Standards Control Organization), India, and a valid WHO GMP certificate during the currency of contract or till the supplies are completed. The Purchaser will not extend any assistance for registration of the product |

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| GCC 6.2 | Effective Date of the Contract is the date of Notification of Award |
| GCC 6.3 | Not Used. |
| GCC 8.1 | Performance security shall be for an amount equal to 10 (Ten) percent of the contract price.<br><br>**Additional clause**:<br>a) In the event of any amendment issued to the Contract, the Supplier shall, within twenty-one (21) days of issue of the amendment, furnish the corresponding amendment to the Performance Security (as necessary) rendering the same valid in all respects in terms of the Contract, as amended.<br><br>b) The performance security shall be valid till 90 days after the date of completion of the contractual obligations including warranty. |
| GCC 8.3 (a) | Amend the paragraph as under:<br><br>The performance security shall be in the form of a bank guarantee and the named beneficiary shall be "Strategic Alliance Management Services Pvt. Ltd." (acting as procurement agent on behalf of Ministry of Health & Family Welfare Government of India). The bank guarantee shall be issued either by a bank located in the country of the Purchaser (Nationalized or Scheduled Bank in India) or a foreign bank through a correspondent bank located in the country of the Purchaser (Nationalized or Scheduled Bank in India) **to make it enforceable and** acceptable to the purchaser.<br><br>Letter of credit is **not** acceptable |
| GCC 8.3 (b) | GCC 8.3 (b) is deleted. |
| GCC 8.4 | In the event of any amendment issued to the contract, the Supplier shall, within twenty one (21) days of issue of the amendment, furnish the corresponding amendment to the Performance Security (as necessary) rendering the same valid in all respects in terms of the Contract, as amended. |
| GCC 9.1 | For the Goods supplied from within India, the goods shall not be dispatched unless they are inspected and cleared for dispatch by Purchaser's representative. For Goods offered from outside India, the Purchaser reserves the right to inspect prior to shipment at the manufacturer's premises. All goods consumed during testing will be on suppliers account.<br><br>For such goods, the supplier shall submit with each |

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| | consignment, the Batch Certificate of Pharmaceutical Product' in conformity with WHO Certification Scheme. The Batch Certificate shall be issued by the regulatory authority of the exporting country. A certificate issued by the manufacturer will not be acceptable.<br><br>On arrival at the port of entry, for goods dispatched from outside India each consignment shall further be tested by the Drug Controller of India or his representative. For this purpose, the Purchaser shall notify the Drug Controller General of India (DCGI) (or his representative) about the expected arrival of the consignment at the port of entry. On the arrival of the goods, the representative of the Drug Controller General of India (DCGI) will examine/test the consignment and after satisfying himself that the goods conform to the technical specifications, he will clear the consignment. Only such goods are permitted to enter the country which is found to fully conform to the technical specifications. The cost of DCGI inspection/testing will not be charged to the supplier but all goods consumed during testing will be on suppliers account.<br><br>The Supplier will make arrangement for storage of Goods in the port of entry at their cost, and will be responsible for costs arising from the storage, warehousing and demurrage up to thirty (30) days only. Costs for storage, warehousing and demurrage in excess of these thirty (30) days resulting from delays due to quality testing procedure will be borne by the Purchaser. |
| GCC 9.1.(a) | The Supplier shall at the earliest furnish details of number of batches and visits for inspection and testing to enable the pre-dispatch inspection and testing when undertaken.<br><br>The related costs of the pre-shipment inspection for the first inspection of goods shall be borne by the Purchaser. However, if goods are offered for inspection in smaller lots than specified in contract then supplier will have to bear the additional inspection charges. The goods consumed during tests will be on suppliers account. The cost of subsequent inspections and related costs, due to rejection of Goods at the first inspection shall be borne by the Supplier. Inspection will be done by a Purchaser's agent to ascertain whether the Goods are in conformity with the technical specifications of the contract or not.<br><br>The Supplier shall put up the goods for such inspection to the Purchaser's inspector 15-25 days (depending on the time |

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| | required for pre-dispatch inspection & testing) ahead of the contractual delivery period, so that deliveries to the consignees are completed as per the contractual delivery period. |
| GCC 9.1(c) | Replace “10 days” to “21 days”.<br><br>Add the following at the end of this clause<br><br>Regardless of any pre-shipment inspection (and the result thereof) undertaken by the Purchaser, the Purchaser/Consignee may inspect and/ or test the Goods at final destination. Unless the full quantity of Goods supplied according to the Schedule of Requirements/each shipment is received in good condition and conform to the specification, the Consignee will not accept the “Goods” and will not issue the acceptance certificate |
| GCC 10.2 | Packing and Marking shall be strictly as per Technical Specifications and will be inspected in terms of provisions of specifications before clearing for dispatch. The Bar coding requirement shall also be properly understood and marked on the package as per the provision of the specification. |
| GCC 11.1 & 11.3 | **The details of shipping and/or other documents to be furnished by the Supplier are:**<br><br>**1 For Goods supplied from abroad**:<br><br>**(A): Documents to be submitted to purchaser:-**<br>Upon shipment, within 24 hours the Supplier shall notify the Purchaser in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and port of shipment, mode of shipment, estimated dates of arrival at the port of entry and the place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of Seventy-Two (72 hours) ahead of dispatch, the name of the carrier, the flight number, the expected date and time of arrival, the Master airway-bill and the House airway- bill numbers. The Supplier shall first fax the above details and then send to the Purchaser, by courier the following:<br><br>(i) One original and three copies of the suppliers commercial invoice, indicating the SAMS as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India; the Contract number, credit number, Goods description, quantity, unit price, and total amount. Invoices must be |

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| | signed in original and stamped, or sealed with the company stamp/seal<br><br>(ii) Four copies of negotiable, clean, on-board through bill of lading/Airway bill marked "freight prepaid" and indicating the SAMS as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India, and notify Consignees as stated in the Contract.<br><br>(iii) Four copies of the packing list identifying contents of each package;<br><br>(iv) One original and three copies of the manufacturer's or Supplier's Warranty Certificate covering all items supplied;<br><br>(v) One original and three copies of supplier's Certificate of country of origin covering all items supplied;<br><br>(vi) Four copies of the Internal Test Analysis Report of the Manufacturer for the items offered<br><br>(vii) Four copies of Inspection certificate furnished to supplier by the nominated agency (where inspection is required)<br><br>(viii) Certificate of quality control test results in conformity with the WHO "Certification Scheme on the quality of Pharmaceutical products moving in International Trade" stating quantitative assays chemical analysis, sterility, pyrogen content, uniformity, and other tests as appropriate to the Goods<br><br>(ix) One original and six copies of the certificate of weight issued by the port authority/licensed authority<br><br>The above sets of documents shall be received by the Purchaser at least 72 hours before the arrival of Goods at the port or place of arrival and, if not received, the Supplier will be responsible for any consequent expenses.<br><br>**(B) Documents to be submitted to Consignee:-**<br>The Supplier shall intimate the Consignee in advance at least 7 days before the dispatch of Goods the expected date of arrival of Goods with quantity. Along with each consignment the Supplier shall provide the Consignee one |

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| | set of the documents mentioned below:<br><br>(i) Supplier's Delivery note, indicating Goods' description, quantity, batch number, date of expiry etc. Delivery note must be signed in original and stamped or sealed with the company stamp/seal;<br><br>(ii) Packing list identifying contents of each package<br><br>(iii) Manufacturers or Supplier's Warranty certificate covering all items supplied.<br><br>(iv) Clearance of the Goods by the drug controller of India at port of entry in term of the SCC Clause 9.1.1<br><br>(iv) Inspection Certificate in case of Pre Dispatch Inspection.<br><br>(v) Country of Origin certificate<br><br>**II. For Goods from within the Purchaser's country:**<br><br>**(A) Documents to be submitted to purchaser:-**<br>Upon the delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver to the Purchaser four sets of documents comprising of the following:<br><br>(i) One original and three copies of commercial invoice, indicating the SAMS as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India, the Contract number, credit number; Goods' description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;<br><br>(ii) Four copies of Proof of Dispatch (POD), viz., Railway consignment note/road consignment note or multimodal transport document showing Purchaser as SAMS on behalf of Ministry of Health & Family Welfare, Govt. of India and delivery up to final destination as stated in the Contract<br><br>(iii) One original & 3 (three) copies of Acknowledgement of receipt of Goods/Final Acceptance Certificate by the Consignees, as per the format.<br><br>(iv) Four copies of packing list identifying contents of each |

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| | package<br><br>(v) One original and three copies of the manufacturer's or Supplier's Warranty certificate covering all items supplied<br><br>(vi) One original and three copies of the Supplier's Certificate of Origin covering all items supplied<br><br>(vii) Four copies of Certificate of Inspection furnished to Supplier by the nominated inspection agency (where inspection is required)<br><br>(viii) Four copies of Internal Test Analysis Report of drugs and pharmaceuticals of the Manufacturer<br><br>(ix) Four copies of notification of the local tax authority in support of rate of tax indicated in invoice.<br><br>(x) Any other/additional procurement-specific document(s) required for delivery/payment purposes.<br><br>**(B) Documents to be submitted to Consignee:-**<br>The Supplier should intimate the Consignee in advance at least 7 days before the dispatch of Goods, the expected date of arrival of Goods along with quantity of Goods. Along with each consignment the Supplier should provide the Consignee one set of the documents mentioned below:<br><br>(i) Copy of NOA<br><br>(ii) Copy of Invoice containing particulars as per Para II(A)(i) above;<br><br>(iii) Packing list identifying contents of each package<br><br>(iv) Manufacturer's or Supplier's Warranty certificate covering all items supplied.<br><br>(v) Country of Origin certificate<br><br>**For both I and II above:** |
| GCC 12.1 | The insurance shall be in an amount equal to 110 percent of the CIP value of the Goods from "warehouse" to "warehouse" |

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| | on “All Risks” basis, including war risks and strikes showing purchaser as Beneficiary. |
| GCC 14.1 | Incidental services to be provided are:<br><br>(a) The Supplier shall provide all necessary licenses and permissions for use of the Goods in India that may be required for the Goods. The cost shall be deemed included in the Contract Price.<br><br>(b) The Supplier shall provide such other services as are stated in the Technical Specifications. |
| GCC 15.2 | The period mentioned as three months to be read as **full period of shelf life of goods**. |
| GCC 15.4 | The period for the replacement of defective goods is: 30 days.<br><br>The date of receipt of replacement supplies at consignee will be treated as the date of delivery for the purpose of calculation of liquidated damages. |
| GCC 16.1 & 16.4 | The method and conditions of payment to be made to the Supplier<br>(Payments will not be made to any other party) under this Contract, as<br>applicable under (A) or (B) below, shall be as follows:<br><br>**(A) Payment for Goods supplied from abroad:**<br>Payment of foreign currency portion shall be made in the Indian currency in the following manner:<br><br>**(i) On Delivery to Consignee: Ninety (90) percent** of the Contract Price of the Goods delivered to the Consignee shall be paid within Sixty (60) days of submission of documents specified in GCC Clause 11 above along with Acknowledgement of receipt of Goods (Form 16), by electronic clearing system of the Bank to the Supplier’s nominated bank account.<br><br>**(ii) On Acceptance**: **Ten (10) percent** of the Contract Price of Goods received shall be paid within sixty (60) days of acceptance of the Goods upon submission of an invoice (indicating SAMS as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India); the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company |

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| | stamp/seal) supported by the Final Acceptance Certificate (Form-17) issued by the Consignee through ECS of the bank.<br><br>Payment of local currency portion shall be made in Indian Rupee within sixty (60) days of presentation of an invoice (indicating the SAMS as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India) the Contract number, credit number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Consignee<br><br>**(B) Payment for Goods and Services supplied from within the Purchaser's country:**<br><br>Payment for Goods and Services supplied from within the Purchaser's country shall be made in Indian Rupee, as follows:<br><br>**(i) On Delivery to Consignee**: **Ninety (90) percent** of the Contract Price of the Goods delivered to the Consignee shall be paid within 60 days of submission of documents specified in GCC Clause 11 along with the Acknowledgement of receipt of Goods (Form 16 of the bid document) through ECS of the bank.<br><br>**(ii) On Acceptance**: **Ten (10) percent** of the Contract Price of Goods received shall be paid within sixty (60) days of acceptance of the Goods upon submission of an invoice (indicating the SAMS, as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India; the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Final Acceptance Certificate (Form 17 of the bid document) issued by the Consignee through ECS of the bank. |
| GCC 17.1 | Prices shall be fixed and firm for the duration of the Contract. However sales tax/VAT wherever payable shall be paid as applicable at the time of supply. |
| GCC 20.1 | Assignment and sub-contracting, which is not disclosed in bid, are not permitted. |
| GCC 22.1 | Applicable rate of LD is **0.5 percent** per week or part thereof. |

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| | Maximum deduction shall be **10 percent** of the delivered price of the delayed goods. |
| GCC 27.2.2 | The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 27.2.2 shall be as follows:<br><br>**A: For Domestic Supplier**<br><br>(a) In case of Dispute or difference arising between the Purchaser and a domestic supplier relating to any matter arising out of or connected with this agreement, such disputes or difference shall be settled in accordance with the Arbitration and Conciliation Act, 1996. The arbitral tribunal shall consist of 3 arbitrators one each to be appointed by the Purchaser and the Supplier. The third Arbitrator shall be chosen by the two Arbitrators so appointed by the Parties and shall act as Presiding arbitrator. In case of failure of the two arbitrators appointed by the parties to reach upon a consensus within a period of 30 days from the appointment of the arbitrator appointed subsequently, the Presiding Arbitrator shall be appointed by the Medical Council of India.<br><br>(b) The Arbitration and Conciliation Act of 1996 the rules herewith and any statutory modification or re-enactment thereof shall apply to arbitration proceedings<br><br>(c) Where the value of the contract is Rs.10 million and below, the disputes or differences arising shall be referred to the Sole Arbitrator. The Sole Arbitrator should be appointed by agreement between the parties; failing such agreement, by the Medical Council of India.<br><br>(d) If one of the parties fails to appoint its arbitrator in pursuance of sub-clause (a) above, within 30 days after receipt of the notice of the appointment of its arbitrator by the other party, then the Medical Council of India shall appoint the arbitrator. A certified copy of the order of the Medical Council of India making such an appointment shall be furnished to each of the parties.<br><br>(e) The venue of Arbitration shall be the place from where the contract is issued and the language of the arbitration proceedings and that of all councils and communications between the parties shall be English. |

(f) The decision of the majority of arbitrators shall be final and binding upon parties. In case there is no majority decision, the decision of the Presiding arbitrator shall be final. The cost and expenses of Arbitration proceedings will be paid as determined by the arbitral tribunal. However, the expenses incurred by each party in connection with the preparation, presentation, etc. of its proceedings as also the fees and expenses paid to the Counsel appointed by such party or on its behalf shall be borne by each party itself.

**B. For Foreign Supplier:**

(a) In case of Dispute with a foreign supplier, the dispute shall be settled in accordance with provision of UNCITRAL (United Nations Commission on International Trade Law) Arbitration Rules. The Arbitral Tribunal shall consist of 3 Arbitrators one each to be appointed by the Purchaser and the Supplier. The third Arbitrator shall be chosen by the two Arbitrators so appointed by the Parties and shall act as presiding arbitrator. In case of failure of the two arbitrators appointed by the parties to reach upon a consensus within a period of 30 days from the appointment of the arbitrator appointed subsequently, the Presiding Arbitrator shall be appointed by the Medical Council of India.

(b) If one of the parties fails to appoint its arbitrator in pursuance of sub-clause (a) above, within 30 days after receipt of the notice of the appointment of its arbitrator by the other party, then the Medical Council of India, shall appoint the arbitrator. A certified copy of the order of the Medical Council of India making such an appointment shall be furnished to each of the parties.

(c) The venue of Arbitration shall be the place from where the contract is issued and the language of the Arbitration Proceedings and that of all councils and communications between the parties shall be English.

(d) The decision of the majority of arbitrators shall be final and binding upon parties. In case there is no majority decision, the decision of the Presiding arbitrator shall be final. The cost and expenses of Arbitration Proceedings will be paid as determined by the arbitral tribunal.

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| | However, the expenses incurred by each party in connection with the preparation, presentation, etc. of its proceedings as also the fees and expenses paid to the Counsel appointed by such party or on its behalf shall be borne by each party itself. |
| GCC 29.1 | The governing language of the contract shall be **English**. |
| GCC 30.1 | Laws of Union of India. |
| GCC 31.1 | The Purchaser's addresses for notice purposes is:<br><br>**Strategic Alliance Management Services Pvt. Ltd. (SAMS),**<br>**1/1B, Choudhary Hetram House, Bharat Nagar,**<br>**New Friends Colony, New Delhi 110025, INDIA**<br>**Phones: 8800257774, 9958994797, 011-41653612**<br>**Email:** pronaco@samsconsult.com<br><br>The Supplier's address for notice purposes is: As mentioned in NOA. |
| GCC 32.1 | Add the following at the end:<br><br>"In addition, the supplier shall be responsible for all taxes, duties, license fees, Octroi, road permit fees etc., incurred in Purchaser's country until delivery of the contracted Goods to the Purchaser |
| GCC 32.2 | Add the words "Octroi, road permits" between words "fees and etc". |

# *SECTION -VI*

# *SCHEDULE OF REQUIREMENTS*

# SECTION VI
## SCHEDULE OF REQUIREMENTS

## ***Schedule of Requirements for Tablet Methadone Syrup***

| Item no. | Description of Goods | Unit | Quantity | Bid Security in Indian Rupees |
|---|---|---|---|---|
| I | Methadone Syrup (5mg/ml) | Ltrs | 1,314 Ltrs. | 40,000 |
| II | Dispensing Bottles | Nos. | 2 Nos. | |

**Delivery Schedule & Consignee details:** As indicated below

**Terms of Delivery: The delivery is required at the following address:**

**Dr. H Rebachandra Singh,**
**Associate Professor,**
**Department of Microbiology,**
**Regional Institute of Medical Sciences (RIMS),**
**Imphal 795 004, Manipur, India.**

**Delivery Schedule: The delivery is to be made in 3 Lots as under:**

| Supply lot | Month of supply | Quantity to be supplied in Litres |
|---|---|---|
| First (50% of the total quantity) and Dispensing Bottles – 2 Nos. | Within one (1) month of issue of Notification of Award. | 657.0 |
| Second (25% of the total quantity) | Within four (4) months of issue of Notification of Award. | 328.5 |
| Third (25% of the total quantity) | Within eight (8) months of issue of Notification of Award. | 328.5 |

# SECTION-VII

# TECHNICAL SPECIFICATIONS

## PART A: Technical Specifications

***Bidders are required to mention specific information in support of the requirement against each paragraph of the following Technical Specification for the items being supplied.***

| SN. | *Requirement* |
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| **I** | ***Methadone syrup*** |
| 1 | Formulation: Syrup, oral |
| 2 | Strength: 5mg/ml |
| 3 | Physical Properties:<br>Orange/Green apple flavor with sugar |
| 4 | Package:<br>1 liter, plastic bottle |
| 5 | The Shelf-life of the drugs should be 3 years from the date of manufacture. |
| 6 | The supplier shall conform to the rules and regulations laid down in the Narcotic Drug and Psychotropic Substances Act during manufacture, storage and transportation of the Syrup Methadone |
| II | **Dispensing Bottle** |
| 1 | **"Dispensing bottle with bottle top calibrated manual dispenser pump should be provided by the successful bidder. Details regarding the same will be shared at the time of award of contract "** |

## PART B

## TECHNICAL SPECIFICATION – GENERAL

| *Our Minimum Requirements* | **Your Offer (Please fill-in)** Yes/No |
|---|---|
| **1. Product and Package Specifications** | |
| 1.1. The pharmaceuticals and vaccines to be purchased by the Purchaser under this Invitation for Bids are included in the Purchaser's national essential drugs list or national formulary. The required packing standards and labeling must meet Good Manufacturing Practices ("GMP") standards in all respects. | |
| 1.2. Product specifications indicate dosage form (e.g., tablet, liquid, injectable, emulsion, suspension, etc. ) and the drug content (exact number of mg or % v/v with acceptable range). The products should conform to standards specified in one of the following compendia: the British Pharmacopoeia, the United States Pharmacopoeia, the French VIPAL pharmacopoeia, Indian Pharmacopoeia, National Formulary of India, or the International Pharmacopoeia the Standards will be the latest edition. In case the pharmaceutical or vaccine product is not included in the specified compendium, the Supplier, upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing. | |
| 1.3. Not only the pharmaceutical or vaccine item, but also the packaging components (e.g., bottles and closures) should also meet specifications suitable for use in a climate similar to that prevailing in the country of the Purchaser. Stability of drugs should be strongly adhered with reference to temperature & humidity in relation to area of supply, during transportation of drugs and their storage. All packaging must be properly sealed and tamper-proof. | |
| 1.4. Pharmaceuticals and drugs requiring refrigeration or freezing for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry. | |
| **2. Product Information** | |
| 2.1. The following information will be required for each pharmaceutical and vaccine product offered by the Bidder:<br><br>(i) INN (International Non-proprietary Name)<br>(ii) Brand name (if it appears on the label)<br>(iii) Name and address of the manufacturer<br>(iv) Country of Origin<br>(v) Compendia standards<br>(vi) Shelf life of Drugs | |
| 2.2. Upon award, the successful Bidder shall on demand provide a translated | |

| ***Our Minimum Requirements*** | **Your Offer (Please fill-in)** Yes/No |
|---|---|
| version in the language of the bid of the prescriber's information for any specific product the Purchaser may request. | |
| 2.3. Failure to include any of this information may, at the discretion of the Purchaser, render the bid non-responsive. | |
| **3. Expiration Date** | |
| 3.1. All products must indicate the dates of manufacture and expiry. | |
| **4. Recalls** | |
| 4.1. If products must be recalled because of problems with product quality or adverse reactions to the pharmaceutical or vaccine, the Supplier will be obligated to notify the Purchaser, providing full details about the reason leading to the recall, and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable pharmaceuticals or vaccines, or withdraw and give a full refund if the product has been taken off the market due to safety problems. | |
| **5. Labeling Instructions** | |
| 5.1. The label for each pharmaceutical and vaccine product shall meet the WHO GMP standard and include:<br>(i) the INN or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name<br>(ii) the active ingredient, per unit, dose, tablet or capsule, etc.<br>(iii) the applicable pharmacopoeial standard<br>(iv) the Purchaser's logo and code number if required in Part A of these Specifications<br>(v) content per pack<br>(vi) instructions for use<br>(vii) special storage requirements<br>(viii) batch number<br>(ix) date of manufacture and date of expiry. | |
| 5.2. The outer carton should also display the above information. | |
| **6. Details of Packing/Cases** | |
| 6.1. All cases should prominently indicate the following:<br>Purchaser's Part A line and Code numbers<br>(ii) the generic name of the product<br>(iii) date of manufacture and expiry<br>(iv) batch number<br>(v) quantity per case | |
| 6.2. No case should contain pharmaceutical or vaccine products from more than one batch. | |
| **7. Unique Identifier** | |

| ***Our Minimum Requirements*** | **Your Offer (Please fill-in)** Yes/No |
|---|---|
| | |
| 7.1. The Purchaser shall have the right to request the Supplier to imprint a logo on the containers used for packaging and in certain dosage forms, such as tablets, and this will be indicated in Part A of the Technical Specifications. The design of such logo shall be provided to the Supplier at the time of Contract award. | |
| **8. <u>Qualifications of Manufacturer</u>** | |
| 8.1. The bidder shall furnish a certificate from the competent FDRA that the manufacturer of the pharmaceutical or vaccine product covered by this Invitation for Bids is licensed to manufacture these products. | |
| **9. <u>Standards and Quality Assurance Requirements</u>** | |
| 9.1. All products must: | |
| (a) Meet the requirements of manufacturing legislation and regulation of pharmaceuticals or vaccines in the country of origin; | |
| (b) Conform to all the specifications contained herein; and | |
| (c) be certified by a competent authority in the manufacturer's country according to resolution WHO 28-65-B, of the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce". | |
| 9.2. The successful Bidder will be required to furnish to the Purchaser:<br>(a) With each consignment, a certificate of quality assurance test results in conformity with the WHO Certification Scheme concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit and other tests, as applicable to the product being supplied and Part A of these Specifications.<br>(b) Assay methodology of any or all tests if requested.<br>(c) When two or more drugs are combined in single tablet, the information about bio-availability must be supplied.<br>(d) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request. | |
| 9.3. The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms. | |

**THE PRODUCTS OFFERED ARE IN ACCORDANCE WITH THE SPECIFICATIONS AND REQUIREMENTS:** YES /NO

ANY DEVIATION MUST BE LISTED BELOW:

.....
.....
.....
.....

_____

_____

## PART C

## SPECIAL INSTRUCTIONS

| ***Our Requirements*** | **Your Offer (Please fill-in)** |
|---|---|
| 1. Each Bottle, inner carton and nested cartons to have the following words printed DIAGONALLY ACROSS THE LABLE in red ink with bold letters.<br>"GOVERNMENT OF INDIA (NACO) SUPPLY - NOT FOR SALE"<br>The supplier should also ensure marking of unique number on each Bottle, inner carton and nested cartons | Yes/No |
| 2. Life of the product, indicating the date of manufacture and date of expiry should be printed as per Drugs & Cosmetics Act-India | Yes/No |
| 3. Equivalency of Standards & Codes<br>Wherever reference is made in the Technical Specifications to specific standards and codes to be met by the Product to be furnished or tested, the provisions of the latest current edition or revision of the relevant standards or codes in effect shall apply, unless otherwise expressly stated in the Contract. Where such standards and codes are national or authoritative standards that ensure substantial equivalence to the standards and codes specified will be acceptable | Yes/No |
| 4. Packing (Clause 10 of GCC)<br>Add as clause 10.3 of the GCC the following –<br>Packing Instruction: The supplier will have to make unit packing for each Drug. Each unit package will be marked on three sides with proper paint/indelible ink, the following;<br>i)Project : National HIV/AIDS Control Project<br>ii)SAMS Purchase Order No. :<br>iii)Country of origin of Goods :<br>iv)Supplier's Name and :<br>v)Packing list reference number : | Yes/No |
| 5. Each outer packing containing the unit packing should have the following label printed in bold letters in large size.<br>i) Purchaser's Name : MINISTRY OF HEALTH & FAMILY WELFARE, Govt. of India, through SAMS<br>ii) Project : National HIV/ AIDS Control Project<br>iii) SAMS Purchase Order No :<br>iv) Country of origin of Goods<br>v) Supplier's Name | Yes/No |
| 6. Any other labeling requirement which the purchaser may ask at the time of approving the labeling samples | Yes/No |

## PART D

## Inspection & Tests (Clause 9 of GCC)

| ***Our Requirements*** | **Please fill-in** Yes/No |
|---|---|
| The following inspection procedures and tests are required by the Purchaser. | |
| a) Two sets of samples of required quantity of each item will be drawn at random from each batch by the Purchaser's Inspector at the manufacturer's premises & sealed before dispatch. | |
| b) One set of sealed sample will be sent to an independent laboratory selected by the purchaser for conducting the required test to confirm whether the samples conform to the prescribed specification. **Another set of sealed sample will be retained with the testing lab as counter sample till the shelf life.** | |
| c) Inspection note will be issued by the inspector on the basis of test report, accepting or rejecting the batch as the case may be. | |
| d) The Goods will be dispatched only after the above inspection procedure has been followed and inspection note issued to accept the consignment. | |
| e) The Purchaser/consignee shall have the right to draw samples at random from the consignment anytime during the shelf life of the drugs and get them retested to satisfy whether the lots conform to the laid down specifications. In the event of the product failing to conform to specifications, the consignee shall reject that batch of supply and inform the supplier for arranging replacement of the rejected batches at supplier's cost. | |

## PART E

## Bar-coding requirements for all medical supplies

| *Our Requirements* | **Your Offer (Please fill-in)** |
|---|---|
| **Bar coding requirements for all medical supplies** | ***"Comply"/ "Not comply"*** |
| **Section A) Primary packaging (Item level and monocarton level)**<br><br>At individual item level (strip of 10 tablets, syrup bottle, injections, vials etc) and/ or on its monocarton (wherever applicable), are required to have a pre printed barcode on its product packaging using either of the barcode symbologies mentioned below:<br><br>a) GS1 linear barcode symbology (EAN-13/UPC-A/EAN-8) to encode GTIN (Global Trade Identification Number) within the barcode.<br>or<br>b) GSI Data Matrix symbology to encode 14 digits product code (GTIN14) within the barcode and using (01) application identifier (to be used where ptinting space is extremely limited).<br><br>Examples of the same are reproduced at Annexure 'A'.<br><br>All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements. | |
| **Section B) Secondary level Packaging (Intermediate packaging)**<br>At secondary level packaging (e.g. box of 10 strips containing 10 tabs each, pack of 10 vials, pack of 10 injections etc), barcode encoding following information to be stickered or preprinted on secondary packaging:<br><br>1) Product identification Code (GTIN-14 of secondary pack) using application identifier (01).<br>2) Expiry date in **YYMMDD** format using application identifier (17)<br>3) Batch/Lot Number using application identifier (10)<br><br>GSI-128 barcode symbology to be used to generate the barcode.<br><br>Examples of the same are reproduced at Annexure 'B'.<br><br>All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements. | |
| **Section C) Tertiary level packaging (Shipper level packaging)**<br><br>At shipper level packaging , a single label containing two barcodes needs to be generated and stickered . The barcodes will encode following information: | |

| ***Our Requirements*** | **Your Offer (Please fill-in)** |
|---|---|
| **Bar coding requirements for all medical supplies** | ***"Comply"/ "Not comply"*** |
| The first barcode will contain the following information:<br><br>1) Product Identification Code (GTIN-14 of shipper level pack) using application identifier (01).<br>2) Expiry Date in **YYMMDD** format using application identifier (17)<br>3) Batch/Lot Number using application identifier (10)<br><br>The second barcode will contain the following information:<br>1) SSCC (Serial Shipping Container Code) using application identifier (00)<br><br>Examples of the same are reproduced at annexure 'c'.<br><br>All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements. | |

## Annexure “A”

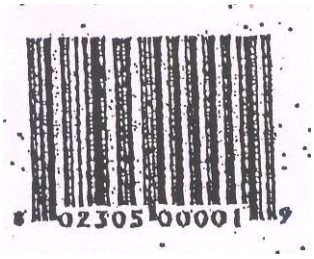
### Examples of Primary Level Packaging

For generation of GSI barcode at primary level packaging either of the mentioned symbologies can be used, following GSI General Specifications.

The following GSI barcode symbologies are available as options :-

1) The barcode sample for EAN-13 barcode symbology encoding GTIN-13


2) The barcode sample for UPC-A barcode symbology encoding GTIN-12




**Note**: Both GTIN-13 GTIN-12 are in extensive use worldwide

3) The barcode sample for EAN-8 barcode symbology encoding GTIN-8 (Used where printing space is a constraint)


4) The barcode sample for GSI Data Matrix barcode symbology encoding GTIN-14 (Used where printing space is extremely limited)

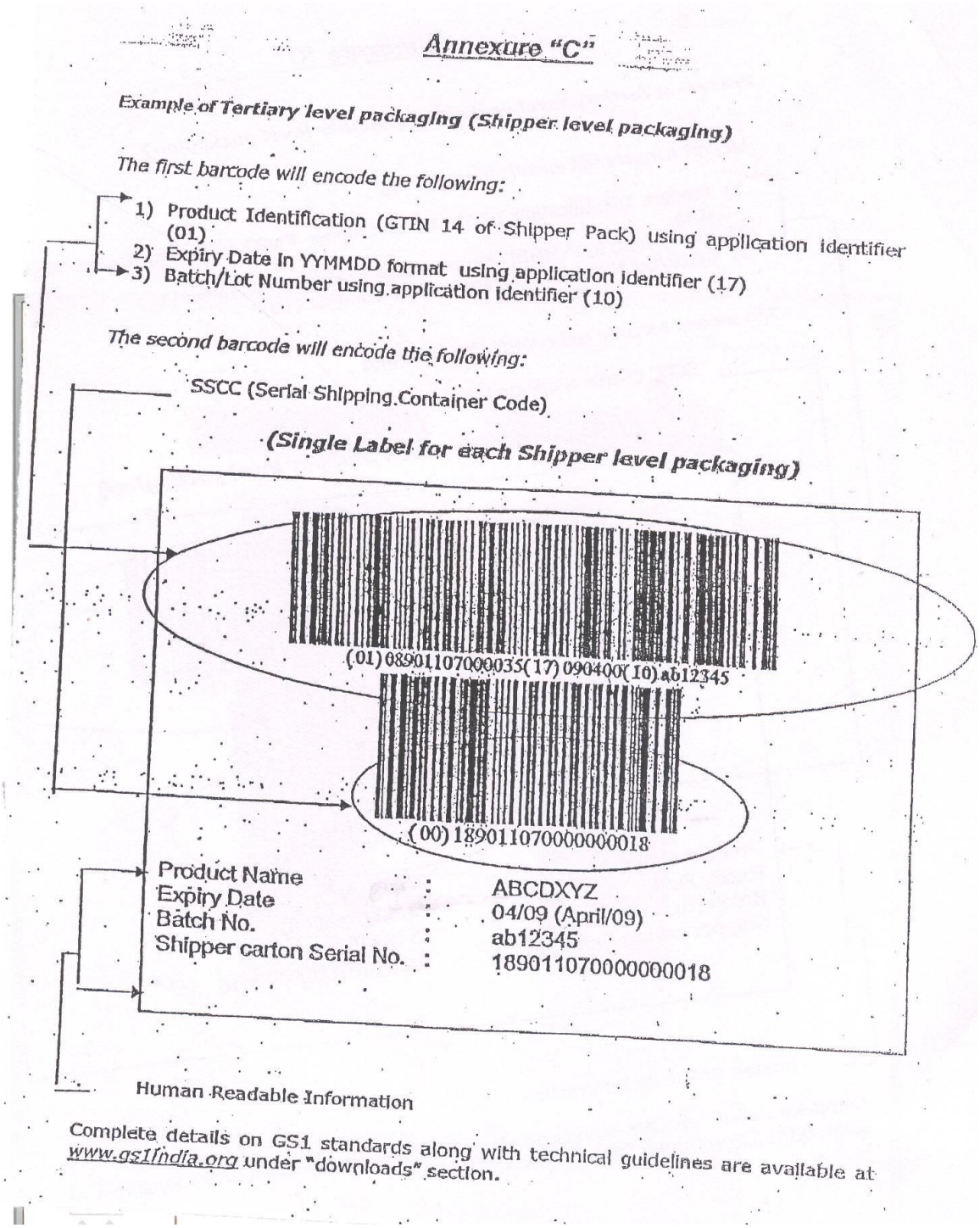
(01)08901107000011

## Annexure “B”

### Example of Secondary level Packaging

The barcode will encode :

1) Product identification (GTIN 14 of secondary pack) using application identifier (01)
2) Expiry date in **YYMMDD** format using application identifier (17)
3) Batch/Lot Number using application identifier (10)


Annexure "C"
Example of Tertiary level packaging (Shipper level packaging)
The first barcode will encode the following:
1) Product Identification (GTIN 14 of Shipper Pack) using application identifier (01)
2) Expiry Date in YYMMDD format using application identifier (17)
3) Batch/Lot Number using application identifier (10)
The second barcode will encode the following:
SSCC (Serial Shipping Container Code)
(Single Label for each Shipper level packaging)
(01) 08901107000035(17) 090400(10) ab12345
(00) 189011070000000018
Product Name : ABCDXYZ
Expiry Date : 04/09 (April/09)
Batch No. : ab12345
Shipper carton Serial No. : 189011070000000018
Human Readable Information
Complete details on GS1 standards along with technical guidelines are available at www.gs1india.org under "downloads" section.

# SECTION -VIII

# SAMPLE FORMS

# SAMPLE FORMS

## *1. Bid Form*

Date: *[ insert: **date of bid** ]*

Loan/Credit No.: *[ Purchaser insert: **number** ]*

*[ Purchaser specify: "IFB No.: [ number ]" ]*

*[ insert: **name of Contract** ]*

To: *[ Purchaser insert: **Name and address of Purchaser** ]*

Dear Sir or Madam:

Having examined the Bidding Documents, including Addenda Nos. *[ insert **numbers** ]*, the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract in full conformity with the said Bidding Documents for the sum of:

| | |
|---|---|
| *[ insert: **amount of local currency in words** ]* | *([ insert: **amount of local currency in figures** ])* |

(hereinafter called "the Total Bid Price") or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

We undertake, if our bid is accepted, to deliver the Goods in accordance with the delivery schedule specified in the Schedule of Requirements.

If our bid is accepted, we undertake to provide an advance payment security and a performance security in the form, in the amounts, and within the times specified in the Bidding Documents.

We agree to abide by this bid, for the Bid Validity Period specified in Clause 18.1 of the Bid Data Sheet and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding Contract between us. We understand that you are not bound to accept the lowest or any bid you may receive.

We undertake that, in competing for (and, if the award is made to us, in executing) the above contract, we will strictly observe the laws against fraud and corruption in force in India namely “Prevention of Corruption Act 1988”.

We hereby certify that we have taken steps to ensure that no person acting for us or on our behalf will engage in bribery. Commissions or gratuities, if any, paid or to be paid by us to agents relating to this bid, and to contract execution if we are awarded the Contract, are listed below:

| Name and Address of Agent | Amount and Currency | Purpose of Commission or Gratuity |
|---|---|---|
| | | |
| | | |
| | | |

(if none, state “none”)

Dated this *[ insert: **number** ]* day of *[ insert: **month** ]*, *[ insert: **year** ].*

Signed: _____

Date: _____

In the capacity of *[ insert: **title or position** ]*

Duly authorized to sign this bid for and on behalf of *[ insert: **name of Bidder** ]*

## *Price Schedule*

( **Schedule No :-**_____

Name of Bidder _____. IFB Number _____. Page _____ of ___.

| 1 | 2 | 3 | 4 | 5 | 6 | | | | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| S.No. | Product | Strength | Dosage form | Qty. offered | Unit prices | | | | Total unit price [a+b+c+d]] | Total price [5 x 7] | Sales and other taxes payable if contract is awarded | Total price including sales and other taxes [8+9] | Rate of sales / other taxes |
| | | | | | [a] EXW (Ex-factory Ex-warehouse Ex-showroom Off the shelf) excluding excise duty | [b] Excise duty | [c] Insurance, Inland transp. & other local costs incidental to delivery | [d] Other incident-al costs as defined in the SCC | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | **Total Bid Price**:<br>In figures:<br>In words: | | | | |

**Note**

a) If the bidder is planning to avail excise duty exemption, kindly do not fill-up excise duty in column 6[b]. Excise Duty, if mentioned above, will be taken in to account while evaluating the bids and the Purchaser will not issue excise exemption certificate in such cases (or if the bid price is “inclusive of excise duty”). If the bid price mentions “exclusive of excise duty” or “excise duty extra”, the purchaser will add the excise duty based on applicable rate during the evaluation of bids and will not issue the issue excise exemption certificate. or sales tax and other taxes, if payable, will be taken in to consideration for evaluation and award of contract purposes.

Signed: _____

Dated: _____

In the capacity of: *[ insert: title or other appropriate designation]*

### *5. Bid Security Form (Bank Guarantee)*

*[The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]*

_____

*[insert **Bank's Name**, and **Address** of Issuing Branch or Office]*

**Beneficiary:** _____ *[insert **Name and Address of Purchaser**]*

**Date:** _____

**BID GUARANTEE No.:** _____

We have been informed that *[insert **name of the Bidder**]* (hereinafter called "the Bidder") has submitted to you its bid dated (hereinafter called "the Bid") for the execution of *[insert **name of contract**]* under Invitation for Bids No. *[insert **IFB number**]* ("the IFB").

Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

At the request of the Bidder, we *[insert **name of Bank**]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert **amount in figures**]* (*[insert **amount in words**]*) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Bidder is in breach of its obligation(s) under the bid conditions, because the Bidder:

(a) has withdrawn its Bid during the period of bid validity specified by the Bidder in the Form of Bid; or

(b) having been notified of the acceptance of its Bid by the Purchaser during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or (ii) fails or refuses to furnish the performance security, in accordance with the Instructions to Bidders.

This guarantee will expire: (a) if the Bidder is the successful bidder, upon our receipt of copies of the contract signed by the Bidder and the performance security issued to you upon the instruction of the Bidder; or (b) if the Bidder is not the successful bidder, upon the earlier of (i) our receipt of a copy of your notification to the Bidder of the name of the successful bidder; or (ii) twenty eight days after the expiration of the Bidder's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

_____

*[signature(s)]*

## *6. Bid Security (Bid Bond)*

**Deleted**

## *7. Bid-Securing Declaration*

**Deleted**

## *8. Manufacturer's Authorization*

*[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Bidder shall include it in its bid, if so indicated in the BDS.]*

Date: *[insert: **date** (as day, month and year) **of Bid Submission**]*
ICB No.: *[insert: **number of bidding process**]*
Alternative No.: *[insert: **identification No if this is a Bid for an alternative**]*

To: *[insert: complete name of Purchaser]*

WHEREAS

We *[insert: **complete name of Manufacturer**]*, who are official manufacturers of *[insert: **type of goods manufactured**]*, having factories at *[insert: **full address of Manufacturer's factories**]*, do hereby authorize *[insert: **complete name of Bidder**]* to submit a bid the purpose of which is to provide the following Goods, manufactured by us *[insert: **name and or brief description of the Goods**]*, and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 15 of the General Conditions of Contract, with respect to the Goods offered by the above firm.

Signed: ***[insert: signature(s) of authorized representative(s) of the Manufacturer**]*

Name: *[insert: **complete name(s) of authorized representative(s) of the Manufacturer**]*

Title: *[insert: **title**]*

Duly authorized to sign this Authorization on behalf of: *[insert: **complete name of Bidder**]*

Dated on _____ day of _____, _____ *[insert: **date of signing**]*

## *9. Form of Contract Agreement*

THIS CONTRACT AGREEMENT is made

the *[ insert: **number** ]* day of *[ insert: **month** ]*, *[ insert: **year** ]*.

BETWEEN

(i) *[ insert: **Name of Purchaser** ]*, a *[ insert: **description of type of legal entity,** for example, an agency of the Ministry of .... of the Government of [ insert: **country of Purchaser** ], or corporation incorporated under the laws of [ insert: **country of Purchaser** ] ]* and having its principal place of business at *[ insert: **address of Purchaser** ]* (hereinafter called "the Purchaser"), and

(ii) *[ insert: **name of Supplier** ]*, a corporation incorporated under the laws of *[ insert: **country of Supplier** ]* and having its principal place of business at *[ insert: **address of Supplier** ]* (hereinafter called "the Supplier").

WHEREAS the Purchaser invited bids for certain goods and ancillary services, viz., *[insert: **brief description of goods and services**]* and has accepted a bid by the Supplier for the supply of those goods and services in the sum of *[ insert: **contract price in words and figures** ]* (hereinafter called "the Contract Price").

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.

2. The following documents shall constitute the Contract between the Purchaser and the Supplier, and each shall be read and construed as an integral part of the Contract:

   (a) This Contract Agreement

   (b) Special Conditions of Contract

   (c) General Conditions of Contract

   (d) Technical Requirements (including Technical Specifications)

   (e) The Supplier's bid and original Price Schedules

   (f) The Purchaser's Notification of Award

   (g) Schedule of requirement

(g) *[Add here: **any other documents**]*

3 In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

4 The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

Brief particulars of the goods and services which shall be supplied/provided by the Supplier are as under:

| SL. NO. | BRIEF DESCRIPTION OF GOODS/SERVICES | QUANTITY TO BE SUPPLIED | UNIT PRICE | TOTAL PRICE |
|---|---|---|---|---|
| | | DELIVERY TERMS | | |
| | | | | |
| | | | | |
| | | | | |

**TOTAL VALUE:**

For and on behalf of the Purchaser

Signed: _____

in the capacity of *[ insert: **title or other appropriate designation** ]*

in the presence of _____

For and on behalf of the Supplier

Signed: _____

in the capacity of *[ insert: **title or other appropriate designation** ]*

in the presence of _____

CONTRACT AGREEMENT

dated the *[ insert: **number** ]* day of *[ insert: **month** ]*, *[ insert: **year** ]*

BETWEEN

*[ insert:* ***name of Purchaser*** *],* “the Purchaser”

and

[ insert: name of Supplier ], “the Supplier”

## *10. Declaration regarding Deemed Export*

**(Name of the Project)**
**(Declaration regarding Deemed Export Benefits)**

(Bidder's Name and Address):

To:.....
(Name of the Purchaser)

Dear Sir:

1 We confirm that we are solely responsible for obtaining deemed export benefits which we have considered in our bid and in case of failure to receive such benefits for reasons whatsoever, Purchaser will not compensate us.

2 We are furnishing below the information required by the Purchaser for issue of Project Authority/ Payment certificate in terms of the Export and Import Policy of the Government of India:

| | | | |
|---|---|---|---|
| (A) | | Value of import content of supply to be made by the Bidder: | Rs. _____ (exchange rate one US$ = Rs ___) |
| (B) | (i) | Name of the sub-contractor, if any and where name is to be included in the main Contract | |
| | (ii) | Description ,quantity and value of the goods to be supplied by the above sub contractor | Description<br>Quantity<br>Value(Rs) |
| | (iii) | Value of import content of supply* to be made by the sub contractor | Rs<br>(exchange rate one US$ =Rs_____) |

*(The requirements listed above are as per current Export and Import Policy of Government of India. These may be modified, if necessary, in terms of the Export and Import Policy in force.)*

Date : _____ (Signature)
_____

Place : _____ (Print Name)

_____

(Designation)

_____

(Common Seal)

_____

*Attach a list, item wise, indicating the value of each

### *11. Proforma for Performance Statement (for a period of last five years)*

Bid No. _____Date of opening_____Time _____ Hours _____

Name of the Firm_____

| Order placed by (full address of Purchaser) | Order No. and Date | Description and quantity of ordered goods | Value of order | Date of completion of delivery | | Remarks indicating reasons for late delivery, if any | Was the supply of pharmaceuticals/Consumables satisfactory* |
|---|---|---|---|---|---|---|---|
| | | | | As per contract | Actual | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

Signature and seal of the Bidder _____

Countersigned by seal of Charted Accountant_____

* The Bidder shall also furnish the following documents in connection with their past performance:

**For supplies within India & for Exports**

a. For supplies made to public sector units in India, an Affidavit confirming that the performance statement given is correct.

b. However in case of supplies to private sector units, an affidavit confirming that the performance statement is correct alongwith following supporting evidence.

i. Copy of Purchase Orders
ii. Copy of Invoices
iii. Proof of Payment received from Purchasers
iv. Documentary evidence (Client's certificate) in support of satisfactory completion of contract

### *12. Qualification Form*

## CAPACITY AND QUALITY CERTIFICATION FORM

## [ RELEVANT COUNTRY AUTHORITY ]

IFB NO. DATE

1 Name of the firm:

Address _____

Telephone _____ Telex

_____

Telefax _____ Cable

_____

a. Name of principals or owner(s):

Address _____

Telephone _____ Telex

_____

Telefax _____ Cable

_____

3_____ (Name of firm) is properly registered to supply pharmaceuticals or vaccines in _____(name of country), is in good legal and statutory standing with the responsible health authorities in that country, and is licensed as a primary manufacturer of the range of pharmaceuticals or vaccines to be offered. (The list of items to be offered is attached).

4 The production capacities for _____ (name of firm) follow:

The installed capacity for this firm is as follows:

| Annual Capacity Non-Sterile | Annual Capacity Sterile |
|---|---|
| Dry: | |
| Tablets | Vials |
| Capsules | Bottles |

Sachets

_____

Wet: Internal
(Liquids and Colloids)

Syrups Tablets
Suppositories I.V. Fluids
Aerosols

External

Liquids Drops/Ointments
Creams
Ointments

5_____ (Name of firm) has manufactured and marketed the specific goods covered by this bidding document offered, for at least one (1) years, and similar goods for at least three (3) years.

6_____ (Name of firm) has experience with and knowledge of modes of packaging, distribution, and transportation of pharmaceuticals or vaccines in countries similar to that of the Purchaser in terms of level of development, climate etc. The following countries have been supplied pharmaceuticals or vaccines worth at least US$ 50,000 within the past five years:

_____
_____

7 We hereby certify that the above information is true and accurate to the best of our knowledge. We understand that the provision of information that is later found to be false is sufficient justification for disqualification.

Signature of the Officer
in relevant Country Authority _____
Date:_____
Full name (Printed)
_____
Position of officer
in relevant Country Authority _____

## *13. Performance Security Bank Guarantee*

_____ *[insert:* ***Bank's Name, and Address of Issuing Branch or Office****]*

**Beneficiary:** _____ *[insert:* ***Name and Address of Purchaser****]*

**Date:** _____

**PERFORMANCE GUARANTEE No.:** _____

We have been informed that *[insert:* ***name of Supplier****]* (hereinafter called "the Supplier") has entered into Contract No. *[insert:* ***reference number of the contract****]* dated _____ with you, for the supply of *[insert:* ***description of goods****]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Supplier, we *[insert:* ***name of Bank****]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert:* ***amount in figures****]* (___) *[insert:* ***amount in words****]*[10] upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation(s) under the Contract, without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire no later than the ____ day of _____, 2_____,[11] and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

---

10 The Guarantor shall insert an amount representing the percentage of the Contract Price specified in the Contract and denominated either in the currency(ies) of the Contract or a freely convertible currency acceptable to the Purchaser.

11 Established in accordance with Clause 8.4 of the General Conditions of Contract ("GCC"), taking into account any warranty obligations of the Supplier under Clause 15.2 of the GCC intended to be secured by a partial performance guarantee. The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months] [one year], in response to the Purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

_____
*[signature(s)]*

# *14. Bank Guarantee Form for Advance Payment*

**DELETED**

## *15. Specimen Certificate of a Pharmaceutical Product*

### Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization *(general instructions and explanatory notes attached).*

No. of certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1Name and dosage form of product:

_____

1.1Active ingredients[2] and amount(s) per unit dose.[3]

_____

_____

_____

For complete qualitative composition including excipients, see attached.[4]

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no *(key in as appropriate)*

1.3 Is this product actually on the market in the exporting country? Yes/no/unknown *(key in as appropriate)*

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.[6]

2A. 1 Number of product license[7] and date of issue:

_____

2A.2 Product-license holder (name and address):

_____

_____

_____

2A.3 Status of product-license holder:[8] a/b/c *(key in appropriate category as defined in note 8)*

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are: [9]

_____

_____

_____

2A.4 Is Summary Basis of Approval appended?[10] yes/no *(key in as appropriate)*

2A.5 Is the attached, officially approved product information complete and consonant with the license?[11] yes/no/not provided *(key in as appropriate)*

2A.6 Applicant for certificate, if different from license holder (name and address):[12]

2B. 1 Applicant for certificate (name and address):

2B.2 Status of applicant: a/b/c *(key in appropriate category as defined in note 8)*

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are:[9]

_____

_____

_____

2B.3 Why is marketing authorization lacking?

Not required/not requested/under consideration/refused *(key in as appropriate)*

2B.4 Remarks:[13]

3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes/no/not applicable[14] *(key in as appropriate)*

If no or not applicable proceed to question 4.

Periodicity of routine inspections (years): _____

Has the manufacture of this type of dosage form been inspected?

Yes/no *(key in as appropriate)*

Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]

yes/no/not applicable[16] *(key in as appropriate)*

2. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? [11]

Yes/no *(key in as appropriate)*

If no, explain: _____

_____

Address of certifying authority: _____

Telephone number: _____ Fax number: _____

Name of authorized person:

_____

Signature:

_____

Stamp and date:

_____

**General instructions**

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

**Explanatory notes**

1 This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2 Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.

3 The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4 Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.

5 When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.

6 Sections 2A and 2B are mutually exclusive.

7 Indicate, when applicable, if the license is provisional or if the product has not yet been approved.

8 Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;

(b) packages and/or labels a dosage form manufactured by an independent company; or

(c) is involved in none of the above.

9 This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Noncompletion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

10 This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

11 This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

12 In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.

13 lease indicate the reason that the applicant has provided for not requesting registration:

(a) The product has been developed exclusively for the treatment of conditions— particularly tropical diseases— not endemic in the country of export.

(b) The product has been reformulated with a view to improving its stability under tropical conditions.

(c ) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.

(d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.

(e) Any other reason, please specify.

14 Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15 The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

16 This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product.

In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

The layout for this Model Certificate is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

### *16. Acknowledgement of Receipt of Goods (for 90% Payment)*

***(This certificate is to be issued in three Original: One Original for SAMS, One Original for Supplier and One Original for NACO.)***

No. Date

To

Strategic Alliance Management Services Pvt. Ltd,
1/1 B, Choudhary Hetram House, Bharat Nagar, New Friends Colony, New Delhi 110025, INDIA

This is to certify that the Goods as detailed below have been received duly inspected in good condition in accordance with the conditions of the contract and amendment if any.

| | |
|---|---|
| Project Name | :National HIV/AIDS Control Programme |
| Purchaser | :SAMS, Delhi, on behalf of MoH&FW (NACO) |
| Contract i.e. NOA No. & Date | : |
| Description of Goods (Schedule No.) | : |
| Delivery Lot No. | : |
| Quantity supplied in Numbers | : |
| Quantity supplied in Words | : |
| Name of Supplier | : |
| Batch No(s). | : |
| Manufacturing Date(s) | : |
| Expiry Date(s) | : |
| Invoice No. and Date | : |
| Date of delivery at Consignee destination site | : |
| Outstanding/dues with the supplier as per NOA & amendment, if any | : |
| Consignee full Address: | Signature of Designated Consignee :<br><br>Name :<br>Designation :<br>Seal :<br>Contact No. :<br>Fax No. : |

**Note: In addition to sending this document through post, it is requested to send a scanned copy by email to pronaco@samsconsult.com also.**

Copy To:

(1) To Supplier

(2) Under Secretary (Admn. P&C, Proc), National AIDS Control Organization, Ministry of Health & Family Welfare, 9th Floor, Chanderlok Building, 36, Janpath, New Delhi – 110001, Fax: 011-23731746

## *17. Final Acceptance Certificate (for Balance 10% Payment)*

***(This certificate is to be issued in three Original: One Original for SAMS, One Original for Supplier and One Original for NACO.)***

No. Date

To

Strategic Alliance Management Services Pvt. Ltd,
**1/1 B, Choudhary Hetram House, Bharat Nagar, New Friends Colony, New Delhi 110025, INDIA**

| | |
|---|---|
| Project Name | :National HIV/AIDS Control Programme |
| Purchaser | :SAMS, Delhi on behalf of MoH&FW (NACO) |
| Contract i.e. NOA No. & Date | : |
| Description of Goods (Schedule No.) | : |
| Delivery Lot No. | : |
| Quantity supplied in Numbers | : |
| Quantity supplied in Words | : |
| Name of Supplier | : |
| Batch No(s). | : |
| Manufacturing Date(s) | : |
| Expiry Date(s) | : |
| Invoice No. and Date | : |
| Date of Final Acceptance | : |
| **CERTIFICATE**<br><br>We confirm having received material as detailed above in good condition on _____ in accordance with the contract and entered in the Stock ledger. | |
| Consignee full Address: | Signature of Designated Consignee :<br><br>Name :<br>Designation :<br>Seal :<br>Contact No. :<br>Fax No. : |

**Note: In addition to sending this document through post, it is requested to send a scanned copy by email to pronaco@samsconsult.com also.**

Copy To:

(1) To Supplier

(2) Under Secretary (Admn. P&C, Proc), National AIDS Control Organization, Ministry of Health & Family Welfare, 9th Floor, Chanderlok Building, 36, Janpath, New Delhi – 110001, Fax: 011-23731746

## *18. Affidavit (On Stamp Paper)*

I _____ son/daughter of _____ resident of _____ solemnly undertake that I am an authorized signatory of M/s _____ *(insert name of the company with full address)* and I hereby undertake that the supplies for which payments are being made have been correctly made to the respective consignees. I take full responsibility for the correctness of the documents submitted for which the payment has been claimed. I further undertake that without prejudice to the rights of purchaser as per the contract, I shall be solely responsible if any of the document is found to be fake even to make good any loss suffered by the purchaser due to incorrectness of the documents submitted by us for claiming payment against invoice(s) no(s)._____ *(insert details of invoices for which payments are being claimed) amounting to*_____*.*

Name: _____

Address: _____

(Supplier full address)

Witness 1 _____

Address:_____

Witness 2 _____

Address _____

**Note:**

1. The affidavit is to be submitted on a non judicial stamp paper of Rs 100 /-(Rupee Hundred) duly notorised and to be signed by the authorized signatory of the firm.
2. This affidavit is to be submitted along with the invoices at the time of claiming 80% payment.

## *19. Proforma for other Details of Bidder, Manufacturer and its Bank*

1. Name & full address of the Manufacturer:

2. (a) Telephone & Fax No Office /Works
   (b) Telex No. Office/Works
   (c) Telegraphic address :
   (d) Email

3. Location of the manufacturing factory.

4. Name & full address of the Bidder

5. (a) Telephone/Mobile & Fax No
   Office/Factory/Works
   (b) Telex No. Office/Works
   (c) Telegraphic address:
   (d) Email

6. Details of two Persons that SAMS may contact for requests for clarification during bid evaluation:

| | 1st | 2nd |
|---|---|---|
| (i) Name:<br>(ii) Tel number (direct):<br>( iii)Mobile No.<br>(iv) Email address | | |

7. Bank details from where the Bank Guarantee for Bid Securityhas been issued:

(i) Name and address of the Bank:
(ii) For a foreign bank, name of correspondent Bank in India:
( iii) Name of the contact Person
(iv) Phone number/Mobile
(v) Fax Number
(vi) Email address

Signature and seal of the Bidder

## *20. Breakup of EXW price as required for determining eligibility for Domestic Preference*

**EXW Price……**

| Serial No. | Item | Cost |
|---|---|---|
| 1 | **Cost of Local labor** | |
| 2 | **Cost of Raw materials procured from within India** (list attached) | |
| 3 | **Cost of Components from within India** (list attached) | |
| 4 | **Total Cost (1+2+3)** | |
| 5 | **Cost of labor, raw materials, and components form within India as a percentage of EXW Price** | |

Attached detailed list of (a) raw materials, and (b) components from within India indicating cost of each.

## *21. Manufacturing Site Inspection Checklist*

- ***This Check list is only for the information purpose and not for filling & submitting with the bids.***
- ***In case The Purchaser wants to conduct an inspection, the Bidder has to be ready, with the filled check list before inspection.***

### Self Appraisal Check List

**(*To be filled by the Manufacturing Firm. The Inspecting Team at the time of inspection will verify the furnished statement and quality rating will be made on the basis of stipulated bench marks*.)**

### Scope

The appropriate section of the checklist should be utilized by the manufacturer of Pharmaceutical doses form to give facts about the facilities.

The checklist covers the following areas

1.1. Location and surrounding
1.2. Building and premises
1.3. Water system
1.4. Disposal of waste
2.0 Warehousing Area
3.0 Production Area.
4.0 Ancillary Areas

5.0 Quality Control Area.

6.0 Personnel.

7.0 Health, Clothing and sanitation of workers.

8.0 Manufacturing Operations and Controls.

8.1. Precautions against mix-up and cross- contamination.

9.0. Sanitation in the manufacturing premises.

10.0. Raw materials

11.0. Equipment.

12.0. Documentation and records.

13.0. Labels and other printed materials.

14.0. Quality Assurance.

15.0. Self Inspection and Quality Audit.

16.0. Quality Control System.

17.0. Specification.

18.0. Master Formula records.

19.0. Packaging Records.

20.0. Batch Packaging Records.

21.0. Batch Processing Records.

22.0. Standard Operating Procedures (SOPs) and Records, regarding.

- 22.1. Sampling.
- 22.2. Batch Numbering.
- 22.3. Testing.
- 22.4. Records of analysis.

23.0 Reference samples.

24.0 Reprocessing And Recoveries.

25.0 Distribution Records.

26.0 Validation and Process Validation.

27.0 Product recalls.

28.0 Complaints and Adverse Reactions.

29.0 Site Master File.

Part IA: - Specific requirements for manufacture of sterile products, Parenteral preparations (small volume injectables and large Volume parenterals) and sterile ophthalmic preparations.

**PART IB: - Specific requirements for manufacture of oral solid dosage Forms (Tablets and Capsules)**

PART IC: - Specific requirements for manufacture of oral liquids (syrups, elixirs, emulsions and suspensions).

PART ID: - specific requirements for manufacture of topical products, i*.e.* External preparations (creams, ointments, pastes, Emulsions, lotions, solutions, dusting powders and identical Products)

- The questions in this checklist included reference to Schedule-M.
- Technical Agreement between CONTRACT GIVER AND CONTRACT ACCEPTOR.

## Data to be provided by the manufacturer

| | |
|---|---|
| **Name of the firm:** | |
| **Address (Head Quarter):** | |
| a. Address (Manufacturing site): | |
| b. Constitution of the Firm (Enclose copy of the constitution | |
| c. Telephone No. of Firm:<br>Head Quarter:<br><br>Manufacturing Site:<br><br>24 Hrs. Contact person's name<br><br>and number: | |
| **Fax No. of the firm:**<br>**Head Quarter:**<br>**Site:** | |
| **E-mail address of the firm:** | |
| **License No. of firm**<br>**(Enclose copy of the license)** | |
| **Categories of drugs manufactured at the site (Clearly specify whether the firm is manufacturing products containing Betalactum, cytostatic / cytotoxic, hormonal, corticosteroids as active ingredient, product with active ingredient from Biological origin or bio technological origin.**<br>**(Enclose list of items licensed at site)** | |
| d. Specify whether following items are manufactured at the site:<br>Dietary supplements, Cosmetic products, Veterinary products, reagents for in-vitro diagnostic use, reagents for in vivo diagnostic use. | |
| e. Production capacity categories wise per shift.<br>***(Enclose list of items being manufactured at site)*** | |
| f. Whether the firm is engaged in contract manufacturing / loan licensing. ***If yes, details thereof.*** | |

| | | |
|---|---|---|
| **Any Certificates/ approval held by the firm (ISO, WHO, USFDA etc,)** | | |
| **Last two years turn over of the firm.** | | |
| **Govt. Supply** | | |
| **Trade** | | |
| **Export** | | |
| **Total (Rupees)** | | |
| **Names of Key Personnel like site head, authorized personnel for manufacturing, quality control, quality assurance, Engineering, procurement, regularly affairs etc. (Enclose organizational chat along with responsibility matrix of key personnel )** | | |
| **List of all equipment section wise along with capacity, make, ID no. and MOC** | | |
| **Whether the site plan is approved. (Enclose copy of the site plan)** | | |

**Checklist**

(Based on Schedule –M and Technical Guidance note to the Industry)

| **1.** | ***LOCATION AND SURROUNDINGS:*** | **Self appraisal to be filled by the manufacturer along with all details (yes or no type reply will not be acceptable)** | **Observations to be noted by the inspecting team at the time of inspection** | **Rating to be made by the inspecting team as per Bench marks** |
|---|---|---|---|---|
| 1.1 | How factory building is situated and controlled to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any other factory which produces disagreeable or obnoxious, odors, fumes, excessive soot, dust, and smoke, chemical or biological emissions.<br>Pls specify industries / establishments adjoining manufacturing site. | | | |
| **1.2** | ***BUILDING AND PREMISES: -*** | | | |
| 1.2.1 | How the building has been designed constructed and maintained to suit the manufacturing operations so as to produce drugs under hygienic conditions.<br>*Pls specify nature of construction used in the facility in respect of its maintenance and hygienic conditions.* | | | |
| 1.2.2 | Whether the building confirm to the conditions laid down in the Factories Act, 1948<br>*Pls attach valid factory certificate/ license issued by the competent authority.* | | | |
| 1.2.3 | Specify how the premises used for manufacturing | | | |

| | | | | |
|---|---|---|---|---|
| | operations and testing purpose prevents contaminations and cross contamination is:<br>a) Compatible with other drug manufacturing operations that may be carried out in the same or adjacent area.<br>Pls specify any special criteria for the product manufacture red. e.g. temperature, humidity, air class requirements maintained for aseptic products, etc. | | | |
| 1.2.4 | b) Whether adequate working space is provided to allow orderly and logical placement of equipment, materials and movement of personnel so as to avoid risk of mix-up between different categories of drugs and to avoid possibility of the contamination by suitable mechanism.<br>Pls specify space left around the machines. Pls attach equipment lay out, men and material movement, waste movement if applicable. | | | |
| 1.2.5 | c) Describe the pest, insects, birds and rodents control system followed in the premises.<br>Attach copy of pest / rodent control schedule along with contract agreement if any. | | | |
| 1.2.6 | d) What measures have been taken to make Interior surface of (walls, floors, and ceilings) smooth and free from cracks, and to permit easy cleaning<br>*Specify material of construction and finish for walls, ceiling, floor, coving etc. i.e. whether Epoxy or PU* | | | |

| | | | | |
|---|---|---|---|---|
| | *coated, kota / granite stone with epoxy sealed joints, solid / GI / gypsum / cal. Silicate board ceiling with epoxy, PU or any other pre-fabricated panel (GRP, powder coated SS or Aluminum etc.) paint.* | | | |
| 1.2.7 | e) What measures have been taken so that the production and dispensing areas are well lighted and effectively ventilated, with air control facilities.<br>Pls specify the lux level maintained in various parts of the premise. | | | |
| 1.2.7.1 | Pls specify the air handling system used in various areas like stores, production, packing, QC areas etc. | | | |
| 1.2.8 | f) Specify drainage system which prevents back flow and entry of insects and rodents into the premises.<br>*(pls specify number and location of drains installed)* | | | |
| 1.3 | ***WATER SYSTEM: -*** | | | |
| 1.3.1 | Whether the unit has validated system for treatment of water drawn from own or any other source to render it potable in accordance with standards specified by BIS or local municipal norms.<br>Pls specify source of raw water and give details of treatment processes, sampling points, distribution and storage system for raw and purified water. | | | |
| 1.3.1.1 | How bio burden in purified water controlled / reduced. | | | |
| 1.3.2 | How water tank are cleaned periodically and records | | | |

| | | | | |
|---|---|---|---|---|
| | maintained thereof. How water distribution system is sanitized to control microbial contaminations. | | | |
| 1.4 | ***DISPOSAL OF WASTE: -*** | | | |
| 1.4.1 | Specify the system of disposal of sewage, and effluents (solid, liquid, and gas) from the manufacturing site.<br>(Enclosed the copy of NOC obtained from State Pollution Control Board in this regard). | | | |
| 1.4.2 | Whether provision for disposal of bio-medical waste made as per the provisions of the Bio Medical Waste (Management and Handling) Rules 1996. | | | |
| 2. | ***WAREHOUSING AREA: -*** | | | |
| 2.1 | Whether adequate areas have been allocated for warehousing of Raw Materials, intermediates, Packaging Material, products in quarantine, finish products, rejected or returned products.<br>How these areas marked or segregated.<br>Please specify the total area provided for warehousing. | | | |
| 2.2 | How the warehousing areas being maintained to have good storage conditions. Are they clean and dry and maintained within acceptable temperature limits? | | | |
| | Specify the storage arrangement provided for materials which sensitive to temperature, humidity and light and how the parameters are monitored.<br>Is cold room or deep freezers | | | |

| | | | | |
|---|---|---|---|---|
| | required for storage of goods? If yes, how the temperature is monitored. | | | |
| 2.2.1 | Whether proper racks, bins and platforms have been provided for the storage. | | | |
| 2.3 | Whether receiving and dispatch bays are maintained to protect in coming and out going materials. | | | |
| 2.3.1 | How incoming materials are treated and cleaned before entry into the plant.<br>Please specify the cleaning system for the outer surface of the container. | | | |
| 2.4 | How quarantined materials are segregated from other materials.<br>How access to quarantined area is restricted. | | | |
| 2.5 | Whether separate sampling area for active Raw Materials and Excipients is provided and maintained.<br>If yes, what is the control on entry of material and men into the sampling area. Whether reverse LAF have been provided for sampling. Whether log book for sampling booth maintained.<br>If not what provision has been made for sampling so as to prevent contamination, cross contamination and mix-ups at a time of sampling. | | | |
| | Specify the arrangements provided to sample the primary packaging materials foils, bottles, etc which are used as such. | | | |
| 2.5.1 | Pls specify sampling plan used. | | | |

| | | | | |
|---|---|---|---|---|
| | Which type of sampling tools are used and how they are cleaned, dried and maintained. | | | |
| | How containers are cleaned before and after sampling. Who carries out the sampling?<br><br>(Pls specify whether the sampling is carried out as per the current SOP). | | | |
| 2.5.2 | What precautions are taken during sampling of photosensitive, hygroscopic materials? | | | |
| 2.6 | What provisions have been made for segregated storage of rejected, recalled or returned materials or products.<br><br>How is the access to these areas restricted? | | | |
| 2.7 | How highly hazardous, poisonous and explosive materials, narcotics, and psychotropic drugs are handled and stored.<br>How these areas are safe and secure.<br>Is there certification from competent authority for handling of explosives etc. If any. Pls attach the certificate issued by the competent authority. | | | |
| 2.8 | How printed secondary packaging materials are stored in safe, separate and secure manner. | | | |
| 2.9 | Specify the arrangement provided for dispensing of starting materials.<br>What is the control on entry of material and men into the dispensing area? Whether reverse LAF have been | | | |

| | | | | |
|---|---|---|---|---|
| | provided for dispensing with back ground clean air supply.<br>Whether pressure differential is maintained between the dispensing and adjacent areas. | | | |
| 2.9.1 | Which type of dispensing tools are used and how they are cleaned, dried and maintained.<br>How containers are cleaned before and after dispensing.<br>Who carries out the dispensing?<br>(Pls specify whether the dispensing is carried out as per the current SOP). | | | |
| 2.10 | How and where sampling of sterile materials carried out. | | | |
| 2.11 | What steps are taken against spillage, breakage and leakage of containers? | | | |
| 2.12 | What provisions have been made to prevent the entry of rodents, insects, birds.<br>Which substance is used for pest control and how it is handled.<br>(Pls specify whether the pest control is carried out as per the SOP). | | | |
| 3. | ***PRODUCTION AREA: -*** | | | |
| 3.1 | Please specify the design of the manufacturing area which allow uni-flow and logical sequence of operations so as to prevent product contamination/ mix ups.<br>Is there any criss cross of flow of materials and men?<br>Specify the position of IPQC lab in the manufacturing area.<br>Please specify whether non storage areas used for storage of any material. | | | |

| | | | | |
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| 3.2 | Whether separate dedicated and self-contained facilities have been provided for the production of sensitive pharmaceutical product like Penicillin, Biological preparation with like micro-organism, Beta lactam, Sex Hormones and Cytotoxic substances.<br>If yes pls explain how and attach copy of plan of premises of each category of drug. | | | |
| 3.3 | Please specify the provisions of storage of dirty, washed and cleaned equipment parts, tool room, in process storage areas etc. Which provide sequential / logical manner so as to prevent contamination and cross contamination? | | | |
| 3.4 | Please specify how service lines like pipe work, electrical fittings, ventilation openings etc. are identified by colors for nature of supply and direction of the flow.<br>Whether service lines in production areas are through service pendants.<br>If not, how they are placed so as to avoid accumulation of dust. | | | |
| 4. | ***ANCILLARY AREAS: -*** | | | |
| 4.1 | Please specify the position of rest and refreshment rooms and mention whether they are separate and not leading directly to the manufacturing and warehouse areas. | | | |
| 4.2 | Are there general change rooms in plant?<br>Are toilets, change room | | | |

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| | separate from mfg. Area? Pls specify number of washing station & toilets provided for number of users.<br>Whether change facilities separated for both sexes.<br>How many sets of protective garments provided for each personnel entering production area.<br>Is there in house general laundry for garment washing / cleaning? If not how garments washing are carried out and monitored. | | | |
| 4.3 | Whether maintenance workshop is separate and away from production. | | | |
| 4.4 | Whether animals for production or testing are housed in the facility if so whether areas housing animals are isolated from other areas.<br>Please specify the provision of air conditioned and ventilation system for the animal house.<br>How quarantined, under test and tested animals housed and controlled.<br>How animal carcass are disposed of.<br>Pls attach copy of CPCSEA. | | | |
| 5. | ***QUALITY CONTROL AREA: -*** | | | |
| 5.1 | Whether QC area is independent of production area.<br>Whether QC carries out its own:<br>• physico-chemical testing,<br>• biological testing,<br>• microbiological testing | | | |

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| | & sterility testing and<br>• Instrumental testing.<br>Whether firm is outsourcing testing. If yes names of the testing laboratories contacted or approved. Pls give list of test currently outsourced.<br>In case of contractual testing what are the responsibilities of contract giver and contract acceptor. (Copy of the contract should be enclosed)<br>Are there safety installation such as shower, eye washer, fire extinguisher etc in the laboratory.<br>Is there separate area for humidity chambers for stability studies. How many humidity chambers have been provided. Pls attach stability calendar. | | | |
| 5.2 | Please specify the arrangement provided for handling and storage of test samples, retained samples, reference standards / cultures, reagents.<br>Whether separate area for storage of reagents and glassware provided.<br>Whether separate records room is provided. | | | |
| 5.2.1 | How hazardous or poisonous materials are stored and handled. | | | |
| 5.3 | How environmental conditions are met during the course of storage and testing of samples.<br>Whether separate washing and drying area provided. | | | |
| 5.3.1 | Which grade of glassware are used in assay procedures. | | | |
| 5.3.2 | Whether separate AHU's are provided for biological, | | | |

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| | microbiological and radio iso-topes testing areas with HEPA filter arrangement. | | | |
| 5.4 | Whether separate areas provided for sterility testing within microbiology lab.<br>Whether support areas are under AHU.<br>Whether double door autoclave provided for sterilization of materials. | | | |
| | Whether entry to the sterility area is through three air lock systems.<br>What is the air class of these testing areas and whether pressure difference is maintained in these areas? | | | |
| | Which types of workbenches are provided in these areas for testing?<br>When was the last filter integrity tests performed on HEPA filters. | | | |
| | How waste (cultures etc) disposed of.<br>Whether in case of antibiotic potency testing, statistical proof of the determination of potency and validity of the test carried out. | | | |
| 6. | ***PERSONNEL: -*** | | | |
| 6.1 | Whether the manufacturing and testing of drugs is conducted under approved technical staff<br>Names of Technical Staff alongwith qualification & experience<br><u>For Manufacturing: -</u><br><u>For Analysis:</u> | | | |

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| 6.2 | Please specify whether head of Q.C. is independent of manufacturing unit | | | |
| 6.3 | Name, qualification and experience of the personnel responsible for Quality Assurance function. | | | |
| 6.4 | Whether responsibilities for production and QC laid down and followed. | | | |
| 6.5 | Whether adequate number of personnel employed in direct proportion to the work load. | | | |
| 6.6 | What is the firm's policy on training of personnel at various levels? | | | |
| 7. | ***HEALTH, CLOTHING AND SANITATION OF WORKERS: -*** | | | |
| 7.1 | Whether personnel handling Beta lactam antibiotics are tested for penicillin sensitivity before employment. | | | |
| 7.2 | Whether personnel involved in handling of sex hormones, cytotoxic and other portent drugs are periodically examined for adverse effect. (Pls specify whether the current SOP is followed or not). | | | |
| 7.3 | Whether all personnel prior to employment have undergone medical examination including eye examination and all free from Tuberculosis, skin and other communicable or contagious diseases | | | |
| | Whether there is a SOP for medical examination. | | | |
| | Pls give name and qualification of contracted medical officer for medical examination. | | | |

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| | Whether investigational reports, films of X rays etc. preserved.<br>Whether records of such medical examination are maintained thereof | | | |
| 7.4 | Whether all personnel are trained to ensure high level of personal hygiene.<br>Pls attach training calendar of last two years. | | | |
| 7.5 | Whether proper uniforms and adequate facilities for personal cleanliness are provided.<br>Pls specify nature and type of dress used by the personnel in various areas of operation.<br>How many dress/footwear have been provided to each personnel.<br>Please specify whether cross over bench is in place in the change room and if so whether it rule out the possibility of entering dust particle to the clean side.<br>Whether arrangements provided for cleaning of outside dust and dirt from foot<br><br>Please specify whether hands are disinfected before entering the production area<br>Whether for sterile garments in house clean laundry has been provided. | | | |
| 8. | ***MANUFACTURING OPERATIONS AND CONTROLS: -*** | | | |
| 8.1 | Whether the contents of all vessels and containers used in manufacture and storage is conspicuously labeled with the name of the products. Batch no, Batch Size, and stage of manufacture along with | | | |

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| | signature of technical staff. | | | |
| 8.1.1 | Whether the products not prepared under aseptic conditions are free from pathogens like Salmonella, Escherichia coli, Pyocyanea etc. | | | |
| 8.1.2 | If yes, pls give brief account of measures taken to assure freedom from pathogens. | | | |
| 8.2 | ***PRECAUTIONS AGAINST MIX-UP AND CROSS-CONTAMINATION:*** | | | |
| 8.2.1 | Whether proper AHU, pressure differential, segregation, status labeling have been provided to prevent mix-up and cross-contamination in manufacturing area | | | |
| | Pls specify the areas of dust generation and mechanism involved in controlling the dust. | | | |
| | Do all the areas have their own independent air locks separately for men and material entry. | | | |
| | What criteria of pressure differential has been set for production v/s adjoining areas. | | | |
| | Whether various operations are carried out in segregated areas. | | | |
| 8.2.2 | Whether processing of sensitive drugs like Beta lactum Antibiotics and Sex Hormones is done in segregated areas with independent AHU and proper pressure differentials alongwith demonstration of effective segregation of these areas with records. | | | |
| | Please specify what measures has been taken to prevent | | | |

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| | contamination of products with Beta Lactum Antibiotics, Sex harmons and cyto toxic substances | | | |
| 8.2.3 | What measures has been taken to prevent mix-ups during various stages of production. | | | |
| | Whether equipments use for production are labeled with their current status. | | | |
| 8.2.4 & 5 | Whether packaging lines are independent and adequately segregated. | | | |
| | How line clearance is performed. Whether records of line clearance is maintained according to appropriate checklist. | | | |
| 8.2.6 | Whether separate carton coding area has been provided or online carton coding is performed<br>How carton coding procedure is controlled. | | | |
| 8.2.7 | Please specify how temperature, humidity and air filtration are controlled in the areas where raw material and/or products are exposed and handled. | | | |
| 8.2.8 | How access of authorized persons to manufacturing areas including packaging is controlled. | | | |
| | Whether separate gowning provision is follows before entering into the procedure. | | | |
| 8.2.9 | Whether segregated secured areas for recall or rejected materials or for such material which are to be processed or recovered are provided.<br>Please specify the room No. of such areas in the plant. | | | |

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| 9. | ***SANITATION IN THE MANUFACTURING AREAS:-*** | | | |
| 9.1 | Specify the cleaning procedure of the manufacturing areas.<br>Whether cleaning procedure is validated.<br>Please specify validation protocol No. of the same. | | | |
| 9.2 | Whether the manufacturing areas are used as the general thoroughfare and storage of materials not under process. | | | |
| 9.3 | Whether a routine sanitation program is in place.<br>Please specify detailed account of sanitation proramme specific to various areas, equipment. | | | |
| 9.4 | Dose the location facilitate cleaning of equipment as well as the cleaning of the areas in which they are installed. | | | |
| 9.5 | Whether production area is adequately lit. If yes.<br>Please give lux levels provided in production, visual inspection and other areas. | | | |
| 10 | ***RAW MATERIALS: -*** | | | |
| 10.1 | Whether the hard copies of records of Raw Materials are maintained as per schedule-U. | | | |
| 10.2 | Please specify the procedures followed receiving and processing of in-coming materials (Starting materials and packing material). | | | |
| | Whether first in / first out or first expiry principal has been adopted. | | | |
| 10.3 | How they are labeled and | | | |

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| | stored as per their status – Under Test, Approved and Rejected | | | |
| 10.4 | Whether incoming materials are purchased from approved sources. | | | |
| | What is the procedure for approving the source for incoming materials. | | | |
| | Whether the raw materials are directly purchased from the manufacturers. | | | |
| | Whether list of approved vendors is available to the user. | | | |
| 10.4 | How damaged containers are identified recorded and segregated. | | | |
| 10.5 | Whether each batch of a consignment is considered for sampling, testing and release. | | | |
| | Whether all the containers of each batch of starting materials is sampled for identification test. | | | |
| 10.6 | Whether labels of raw material in the storage area have information like<br>(a) designated name of the product and the internal code reference, where applicable, and analytical reference number;<br>(b) manufacturer's name, address and batch number;<br>(c) the status of the contents (e.g. quarantine, under test, released, approved, rejected); and<br>(d) the manufacturing date, expiry date and re-test date. | | | |
| 10.7 | Whether separate areas are provided for under test, approved and rejected materials. | | | |

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| | How control on temperature and humidity conditions, wherever necessary, maintained in these storage areas. | | | |
| 10.8 | How the containers from which samples have been drawn labeled. | | | |
| 10.9 | Please specify the procedures by which it is ensured that the raw materials which has been released by the Quality Control Department and which are within their shelf life are going to be used in the product. | | | |
| 10.10 | How materials are stacked in the Stores i.e on Pallets, racks etc. | | | |
| 11 | ***EQUIPMENT: -*** | | | |
| 11.1 | Whether the equipments are designed aiming to minimize risk of error and permit effective cleaning in order to avoid cross contamination, build up of dust. | | | |
| | Whether all equipment are provided with log book. | | | |
| | Please specify the procedures to clean the equipment after each batch production. | | | |
| | Whether validity period for use after the cleaning of equipment is specified. | | | |
| | Whether separate area is provided for storage of machine parts etc. | | | |
| 11.2 | Whether balances and other measuring equipments with appropriate range are available in the Raw Material stores & production areas and they are calibrated in accordance with SOP | | | |

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| | maintained.<br>Specify the calibration schedule of the balances. | | | |
| 11.3 | Please specify material of construction of contact parts of the production equipments. | | | |
| 11.4 | Which types of lubricants are used in the equipment.<br>Specify the quality and control reference No. of these lubricants. | | | |
| 11.5 | Specify the procedures to remove defective equipments from production areas. | | | |
| 12 | ***DOCUMENTATION AND RECORDS: -*** | | | |
| 12.1 | How the documents are designed, prepared, reviewed and controlled to provide an audit trail. | | | |
| 12.1.1 | Whether documents are approved signed and dated by appropriate and authorized person. | | | |
| 12.2 | Whether documents specify title, nature and purpose. | | | |
| 12.3 | Whether documents are regularly reviewed and kept up to date. If yes. Please specify review period.<br>Please attached the list of documents maintained by the firm. | | | |
| 12.4 | Whether the records are made at the time of each operation in such a way that all significant activities concerning to the production are traceable. | | | |
| 12.5 | Whether data is recorded by electronic data processing system or by other means. If by electronic data processing system then how access is controlled to enter, modify etc. | | | |

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| | the data. | | | |
| | Whether master formula and detailed operating procedures are maintained as hard copy. | | | |
| | Who is responsible for maintenance of these records. | | | |
| 13 | ***LABELS AND OTHER PRINTED MATERIALS:*** | | | |
| 13.1 | Whether the printing is in bright colour and legible on labels and other printed materials. | | | |
| | How printed labels (art work) are approved. Is there any SOP for this if yes please give current SOP No. | | | |
| | Which colour coding system is used to indicate the status of a product and equipment. | | | |
| 13.2 | How printed packaging materials, product leaflets etc. are stored separately to avoid chances of mix-up. | | | |
| 13.3 | How labels cartons boxes circulars inserts and leaflets are controlled. | | | |
| 13.4 | Whether the samples from the bulk are drawn tested, approved and released prior to packaging and labeling.<br>How carryout the sampling. | | | |
| 13.5 | How records of receipt of all labeling and packaging materials are maintained. | | | |
| | Whether re-conciliation of used packaging materials is maintained.<br>Whether unused packaging materials return to the store or destroyed. | | | |
| | How returned/unused packaging material like foils is controlled so as to prevent contamination and cross- | | | |

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| | contamination. | | | |
| 13.6 | How the labels of reference standard and culture maintained. | | | |
| 14 | ***QUALITY ASSURANCE: -*** | | | |
| 14.1 (a) | Specify the comprehensive quality assurance system maintained by the firm *Inter-alia* to cover deviation, reporting, investigation and change control.<br>How the products are designed and developed in accordance with GMP. | | | |
| (b) | Please specify the arrangements provided to ensure that correct starting and packaging materials are used for manufacture. | | | |
| (c) | Please specify the mechanism by which all control like IP QC Calibration, Validation etc. are ensured. | | | |
| (d) | Please specify the mechanisms to ensure that the finished product has been correctly processed and checked in accordance with the established procedures. | | | |
| (e) | Please specify the mechanisms to ensure that Pharmaceuticals products are released for sale by authorization person. | | | |
| 15 | ***SELF INSPECTION AND QUALITY AUDIT: -*** | | | |
| 15.1 | Whether the firm has constituted a self inspection team supplemented with a quality audit procedure to evaluate that GMP is being followed. If no. How internal audits are carried out. | | | |
| | What is the system of | | | |

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| | monitoring, evaluation of self inspection. | | | |
| | How conclusion and recommended correcting actions are followed and adopted. | | | |
| 15.2 | What is the frequency of self-inspection. | | | |
| 15.3 | Is there any proforma for carrying out the self-inspection.<br>Please indicate the date of last self-inspection. | | | |
| 16 | ***QUALITY CONTROL SYSTEM: -*** | | | |
| 16.1 to 16.3 | Please specify the details of quality control system of the unit. | | | |
| | How the reference standards are stored, evaluated and maintained.<br>Please provide list of reference standard and reference impurities procured from the authentic sources. | | | |
| | Please specify the procedures of preparation of working standard from the reference standards. | | | |
| 16.4 & 16.5 | Whether SOPs for sampling, inspecting, testing of Raw Materials, Finish products, Packing Materials and for monitoring environmental conditions are available. | | | |
| | Whether approved specifications for different materials, products, reagents, solvents including test of identity content, purity and quality available. | | | |
| 16.7 | How reference samples from each batch of the products are maintained. | | | |

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| 16.6 & 16.8 16.9 | Who releases batch of the products for sale or supply. | | | |
| | Whether there is check list for release of a batch. Please specify current SOP No. for batch release. | | | |
| | Please specify the sampling procedures from various stages of production. | | | |
| | How it is ensured that the sample collected are representative of the whole batch. | | | |
| 16.10 16.11 | Please specify the procedures for carrying out the stability studies. | | | |
| | Under what condition stability studies of the products are tested.<br>How many stability chambers have been provided. | | | |
| | How self life is assigned to a product. Please give current stability protocol No. | | | |
| | Whether records of stability studies are maintained. | | | |
| | Please attach stability calendar of last year. | | | |
| | How complaints are investigated. | | | |
| 16.12 | How instruments are calibrated and at which interval. | | | |
| | How testing procedure validated before they are adopted for routine testing. | | | |
| | Specify the validation procedure is responsible for validation of procedures. | | | |
| | How validation procedures are documented (Please indicate various protocols/ recoding system applied during validation). | | | |

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| 16.13 | Whether specifications for raw materials intermediates final products and packaging materials are available. | | | |
| | Whether periodic revision of these specifications are carried out.<br>Please specify No. of STPs being maintained by the firm. | | | |
| 16.14 | Which pharmacopoeias in original are available in the plant. | | | |
| 17 | ***SPECIFICATIONS: -*** | | | |
| 17.1 | Whether specification of raw material include.<br>(a) the designated name and internal code reference;<br>(b) reference, if any, to a pharmacopoeial monograph;<br>(c) qualitative and quantitative requirements with acceptance limits;<br>(d) name and address of manufacturer or supplier and original manufacturer of the material;<br>(e) specimen of printed material;<br>(f) directions for sampling and testing or reference to procedures;<br>(g) storage conditions; and<br>(h) Maximum period of storage before re-testing.<br>Whether specification of finished product include<br>(a) the designated name of the product and the code reference;<br>(b) the formula or a reference to the formula and the pharmacopoeial reference;<br>(c) directions for sampling and testing or a reference to procedures; | | | |

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| | (d) a description of the dosage form and package details;<br>(e) the qualitative and quantitative requirements, with the acceptance limits for release;<br>(f) the storage conditions and precautions, where applicable, and<br>(g) the shelf-life. | | | |
| 17.2 | Whether the container and closures meet the pharmacopial specifications.<br>Whether second hand or used containers and closures used. | | | |
| 18 | ***MASTER FORMULA RECORDS: -*** | | | |
| | How master formula records are prepared, authorized and controlled. | | | |
| | Whether head of production, quality control and quality assurance unit endorse this documents. Whether master formula is batch size specific. | | | |
| | Whether all products have master formula containing.<br>(a) the name of the product together with product reference code relating to its specifications;<br>(b) the patent or proprietary name of the product along with the generic name, a description of the dosage form, strength, composition of the product and batch size;<br>(c) name, quantity, and reference number of all the starting materials to be used. Mention<br>shall be made of any substance that may 'disappear' in the course of processing. | | | |

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| | (d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.<br>(e) a statement of the processing location and the principal equipment to be used.<br>(f) the methods, or reference to the methods, to be used for preparing the critical equipments including cleaning, assembling, calibrating, sterilizing;<br>(g) detailed stepwise processing instructions and the time taken for each step;<br>(h) the instructions for in-process control with their limits;<br>(i) the requirements for storage conditions of the products, including the container, labeling and special storage conditions where applicable;<br>(j) any special precautions to be observed;<br>(k) packing details and specimen labels. | | | |
| 19 & 20 | ***PACKAGING RECORDS: -*** | | | |
| | Whether authorized packaging instructions for each products, pack size and type are maintained and complied with.<br>Whether following are included in the packaging instructions.<br>(a) Name of the product;<br>(b) description of the dosage form, strength and composition;<br>(c) the pack size expressed in terms of the number of doses, | | | |

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| | weight or volume of the product in the final container;<br>(d) complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types with the code or reference number relating to the specifications of each packaging material.;<br>(e) reproduction of the relevant printed packaging materials and specimens indicating where batch number and expiry date of the product have been applied;<br>(f) special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before the operations begin.<br>(g) description of the packaging operation, including any significant subsidiary operations and equipment to be used;<br>(h) details of in-process controls with instructions for sampling and acceptance; and<br>(i) Re-cancellation after completion of the packing and labeling operation.<br>(j) Whether line clearance records are part of batch packing records. | | | |
| 21 | ***BATCH PROCESSING RECORDS (BPR)*** | | | |
| 21.1 | Whether BPR are based on current master formula record.<br>How BPR are designed to avoid transcription errors.<br>Whether the Batch Processing Records for each product on the basis of currently approved master formula is being | | | |

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| | maintained.<br>Whether following information are recorded in BPR<br>(a) the name of the product,<br>(b) the number of the batch being manufactured,<br>(c) dates and time of commencement, significant intermediate stages and completion of production.<br>(d) initials of the operator of different significant steps of production and where appropriate, of the person who checked each of these operations,<br>(e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed,<br>(f) any relevant processing operation or event and major equipment used,<br>(g) a record of the in-process controls and the initials of the person(s) carrying them out,<br>and the results obtained,<br>(h) the amount of product obtained after different and critical stages of manufacture (yield),<br>(i) comments or explanations for significant deviations from the expected yield limits shall be given,<br>(j) notes on special problems including details, with signed authorization, for any deviation from the Master Formula,<br>(k) Addition of any recovered or reprocessed material with reference to recovery or reprocessing stages.<br>Specify the procedures for all the entries made in BPR's. | | | |

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| 22 | ***STANDARD OPERATING PROCEDURE AND RECORDS: -*** | | | |
| 22.1 to 22.5 | Whether SOPs and records are being maintained and complied for the following.<br>SOP for receipt of in coming material<br>(a) SOP for Internal labelling, quarantine, storage, packaging material and other materials<br>(b) SOP for each instrument and Equipment<br>(c) SOP for sampling<br>(d) SOP for batch numbering<br>(e) SOP for testing<br>(f) SOP for equipment assembly and validation<br>(g) SOP for Analytical apparatus and calibration<br>(h) SOP for maintenance, cleaning and sanitation<br>(i) SOP for training and hygiene for the personal<br>(j) SOP for retaining reference Samples<br>(k) SOP for handling, re-processing and recoveries<br>(l) SOP for distribution of the product<br>(m) SOP for warehousing of products.<br>Whether applicable SOPs are available in each area where they are required.<br>Whether recording formats are referred in SOP.<br>Is there SOP for writing an SOP. | | | |
| 23 | **Reference Samples** | | | |
| 23.1 & 2 | Specify the procedures for collection of reference | | | |

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| | samples of active ingredients and finished formulations and how they are stored and maintained. | | | |
| 24 | Reprocessing and Recoveries | | | |
| 24.1 – 24.3 | Specify the procedures for reprocessing.<br>Whether reprocessed batch is subjected to stability evaluation.<br>Whether the recoveries are added into the subsequent batches. If yes specify the procedures. | | | |
| 25 | Distribution records | | | |
| | Whether pre dispatch inspections are carried out before release. | | | |
| | Whether periodic audits of distribution center are carried out to access warehousing practices | | | |
| | Whether distribution records are part of the batch record. If not how batch wise distribution record up to retail levels are maintained. | | | |
| | Whether instruction for warehousing and stocking of products like LVPs, Heat sensitive etc are available in store. | | | |
| 26 | ***VALIDATION AND PROCESS VALIDATION: -*** | | | |
| 26.1 to 26.5 | Specify the validation policy of the company.<br><br>Whether validation master plan has been prepared. | | | |
| | Whether validation studies of processing, testing and cleaning procedures are conducted as per pre defined protocol. | | | |

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| | How records and conclusion of such validation studies are prepared and maintained. | | | |
| | Whether master formula is based on approved process validation. | | | |
| | Specify how significant changes to the manufacturing process equipments material etc are controlled. | | | |
| | Whether DQ,IQ,OQ & PQ are in place for all major equipment and facility. | | | |
| | Whether validation records of all utilities and major equipments are available. | | | |
| 27 | ***PRODUCT RECALLS: -*** | | | |
| 27.1 to 27.6 | Specify the product recall system followed by the firm.<br>How promptly recall operation at the level of each distribution channel up-to the retail level can be carried out.<br>Whether there is a SOP for recall of products clearly defining responsibility, procedure, reporting, re-conciliation etc. | | | |
| 28 | ***COMPLAINTS AND ADVERSE REACTIONS: -*** | | | |
| 28.1 | Specify the review system for complaints concerning the quality of products. | | | |
| | How records of complaint and adverse reactions maintained. | | | |
| | Whether reports of serious drugs reaction with comments and documents immediately sent to Licensing Authority | | | |
| | Is there any criteria for action to be taken on the basis of nature of complaint / adverse reaction. | | | |
| 29 | ***SITE MASTER FILE: -*** | | | |

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| | Whether all the relevant information have been included in the site master file. | | | |
| | Whether quality policy has been included in the site master file.<br>Please attach the current version. | | | |

## Checklist

| | PART-IA<br><br>**(Specific requirements for manufacture of Sterile products, Parenteral preparations (Small Volume Injectable Large Volume Perenterals) and Sterile ophthalmic preparations)** | Self appraisal to be filled by the manufacturer along with all details (yes or no type reply will not be acceptable) | Observations to be noted by the inspecting team at the time of inspection | Rating to be made by the inspecting team as per Bench marks |
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| **1.** | Whether dampness, dirt and darkness is visible in the facility. | | | |
| **2.** | **Building and Civil Works** | | | |
| 2.1 | Whether the building is devoid of cracks especially in the Aseptic solutions preparation rooms, Filling rooms, Sealing rooms | | | |
| 2.2 | Are the location of services like water, steam, gases etc. are such that the servicing or repairs can be carried out without any threat to the integrity of the facility | | | |
| 2.3 | Whether water lines pose any threat of leakage to the aseptic area | | | |
| 2.4 | Whether the manufacturing areas clearly separated into Support Areas (washing and component preparation areas, storage areas etc.) Preparation areas (bulk manufacturing areas, non aseptic blending areas etc) Change areas and Aseptic areas | | | |
| 2.5 | Whether de-cartooning areas to remove outer cardboard wrappings of primary packaging materials segregated from the washing areas | | | |
| 2.6 | Whether particle shedding materials like wooden pallets, | | | |

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| | fiber board drums, cardboards etc taken into the preparation areas etc | | | |
| 2.7a | Whether in the aseptic areas:<br>Walls, floors and ceiling are<br>- Impervious<br>- Non-shedding<br>- Non-cracking<br>- Coved at wall and ceiling junction | | | |
| 2.7b | Whether the walls are flat, smooth and devoid of recesses | | | |
| 2.7c | Whether the surface joints like electric sockets, gas points flushed with walls | | | |
| 2.7d | Whether the ceiling is solid and the joints are properly sealed. | | | |
| 2.7e | e the air grills and lights flushed with the walls | | | |
| 2.7f | *Are the grade A & B areas devoid of sinks and drains* | | | |
| 2.7g | Are the doors and windows made up of non-shedding materials | | | |
| 2.7h | Whether doors open towards higher pressure areas and close automatically due to air pressure | | | |
| 2.7i | *In case fire escapes are provided, whether they are suitably fastened to the walls without gaps* | | | |
| 2.7j | Whether the quality of the furniture used is smooth & washable and made of stainless steel, or of any other suitable material other than wood | | | |
| 2.8 | Whether the Manufacturing and support areas have the same quality of civil structure as desired for aseptic areas except the environmental standards which may vary in the critical areas | | | |
| 2.9 | Is the change rooms entrance provided with air locks before entry to the sterile product | | | |

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| | manufacturing areas and then to the aseptic areas. | | | |
| 2.10 | Are the change rooms to the aseptic areas clearly demarcated like ‘black’, ‘gray’ and ‘white’ with different levels of activity and air cleanliness? | | | |
| 2.11 | Are the sinks and drains in the first change rooms (un-classified) kept clean all the time | | | |
| 2.12 | Do the specially designed drains are periodically monitored to check for pathogenic micro-organisms | | | |
| 2.13 | Whether an appropriate inter-locking system with visual and/or audible warning system installed to prevent the opening of more than one door at a time. | | | |
| 2.14 | Do the aseptic and non-aseptic areas provided with intercom telephones or speak phones for communication purposes | | | |
| 2.15 | Whether the aseptic areas and outside areas provided with suitable air- locks or pass boxes with suitable interlocking arrangements for material transfer | | | |
| 2.16 | Are the rest rooms, tea room, canteen and toilets outside the sterile manufacturing area | | | |
| 2.17 | Are the animal houses outside and away from the sterile product manufacturing area with separate AHU. | | | |
| **3** | **Air Handling System (Central Air Conditioning)** | | | |
| 3.1 | Whether the Air Handling Units for sterile product manufacturing area separate from those for other areas | | | |
| 3.2 | **Give the Background Grade of air for following critical areas:** | | | |
| | • Aseptic filling area | | | |

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| | • Sterilized components unloading area for aseptic filling preparations. | | | |
| | • Sterilized components unloading area for terminally sterilized products. | | | |
| | • Filling room of terminally sterilized products. | | | |
| | • Batch manufacturing area for aseptic filling preparations. | | | |
| | • Batch manufacturing area for terminally sterilized products. | | | |
| | • Component washing and preparation area. | | | |
| | • Final change room (Aseptic Area) | | | |
| 3.3 | Whether Aseptic filling area, sterilized component unloading area and changes rooms conforming to Grade B, C and D have separate Air Handling Units. | | | |
| 3.4 | Are the filter configuration in the air handling system suitably designed to achieve the Grade A, B, C and D of air as per designated classified areas. | | | |
| 3.5 | Whether the types of Operations to be carried out in the various Grades for Aseptic Preparations are as under: | | | |
| a) | **Grade Type of Operation** Aseptic preparation & filling | | | |
| b) | Aseptic Solution preparation to be filtered | | | |
| d) | Handling of components after Washing | | | |
| 3.6 | Whether for aseptically filled products the filling room meet **Grade B** conditions at rest, unmanned within a period of about **30 minutes** of the | | | |

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| | personnel leaving the room after completion of operations | | | |
| 3.7 | Are the filling operations undertaken in **Grade A** conditions and demonstrated under working of simulated conditions | | | |
| 3.8 | Whether the filling room meets **Grade C** conditions at rest in case of terminally sterilized products and these conditions obtainable within a period of about 30 minutes of the personnel leaving the room after completion of the operations | | | |
| 3.9 | Whether the manufacturing and component preparation areas for terminally sterilized products meet Grade C conditions | | | |
| 3.10 | Whether the washed components and vessels for terminally sterilized products protected with Grade C background or if necessary under LAF station. | | | |
| 3.11 | Whether the number of air changes in Grade B and Grade C areas are more than 20 per hour. | | | |
| 3.12 | Whether the Grade A Laminar Air Flow stations meet the criteria of air flow of 0.3 meter per second in case of vertical and that of 0.45 meter per second in case of horizontal flows +/- 20 % | | | |
| 3.13 | Whether the differential pressure between areas of different environmental standards meets the requirements (at least 15 Pascal/ 0.06 inches/ 1.5 mm water gauge) | | | |
| 3.14 | Whether suitable manometers / gauges installed for measurement and verification. Specify type of manometer. | | | |

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| 3.15 | Whether the final change rooms have the same class of air as specified for the aseptic area. | | | |
| 3.16 | Whether the pressure differential in the change rooms is in the descending order, from ' white' to' black'. Specify pressures of three change rooms. | | | |
| **4.** | **Environmental Monitoring** | | | |
| 3.18 | Whether temperature and humidity (NMT 27$^{C}$C and 55 % RH respectively) in the aseptic areas are controlled. | | | |
| 4.1 | Whether the records exist to show that all the environmental parameters were verified at the time of installation and checked periodically thereafter? | | | |
| 4.2 | Are the recommended periodic monitoring frequencies followed | | | |
| a) | Particulate counts - 6 Monthly | | | |
| b) | HEPA filters integrity testing – Yearly | | | |
| c) | Air Change rates - 6 Monthly | | | |
| d) | Air pressure differentials - Daily | | | |
| e) | Temperature and Humidity - Daily | | | |
| f) | Microbiological monitoring by settle plates and/ or swabs in: **Aseptic areas -- Daily, Other areas Decreased frequency** | | | |
| 4.3 | Does a written Environmental Monitoring Program exist? How long the settle plates are exposed in Grade A and other areas. | | | |
| 4.4 | Are the microbiological results recorded | | | |

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| 4.5 | Are these results assessed with recommended limits | | | |
| 4.6 | Do they take action in case particulate and microbiological monitoring counts exceed the limits. | | | |
| 4.7 | In case of major engineering modifications being carried out to the HVAC system of any area, Whether all parameters reassessed and approved before starting production. | | | |
| **5.** | **Garments** | | | |
| 5.1 | Whether Outdoor clothing is allowed in the sterile areas | | | |
| 5.2 | Do they use cotton garments which are not allowed? | | | |
| 5.3 | Are the garments made of non-shedding and tight weaving material? | | | |
| 5.4 | Whether the garments are of suitable design in single piece with fastening at cuffs, neck and at legs to ensure close fit Trouser legs to be tucked inside the cover Boots | | | |
| 5.5 | Whether the garment includes a hood or a separate hood which can be tucked inside the overall. | | | |
| 5.6 | Whether Pockets, pleats and belts are avoided | | | |
| 5.7 | Whether Zips (if any used in garments) are of plastic material | | | |
| 5.8 | Whether the personnel wear only clean, sterilized and protective garments at each work session where aseptic filtration and filling operations are undertaken and at each work shift for products intended to be sterilized, post-filling | | | |
| 5.9 | Are masks and gloves are changed at every work session. | | | |
| 5.10 | Are the gloves used made of latex or other suitable plastic | | | |

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| | material | | | |
| 5.11 | Are powder free gloves used in clean rooms | | | |
| 5.12 | Are the gloves long enough to cover the wrists completely and allow the over-all cuff to be tucked in | | | |
| 5.13 | Are the foot-wear used made of plastic or rubber material | | | |
| 5.14 | Are the foot-wear daily cleaned with a bactericide | | | |
| 5.15 | Does the safety goggles / numbered glasses worn in side the aseptic areas have side extensions | | | |
| 5.16 | Are safety goggles sanitized by a suitable method | | | |
| 5.17 | Whether the garment changing procedure documented | | | |
| 5.18 | Whether the operators trained in garment changing procedure. | | | |
| 5.19 | Whether a full size mirror been provided in the final change room to ascertain that the operator has appropriately attired in the garments | | | |
| **6.** | **Sanitation** | | | |
| 6.1 | Whether written procedures available for sanitation of sterile processing facilities | | | |
| 6.2 | Whether the employees carrying out the sanitation of aseptic areas specially trained for the purpose | | | |
| 6.3 | Whether more than one sanitizing agent is used in rotation. | | | |
| 6.4 | Whether the concentration of the agent used has been recommended by the manufacturer | | | |
| 6.5 | Whether distilled water is used for the dilution of the disinfectant, if so is it directly collected from the distilled water plant or from | | | |

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| | re-circulation loop maintained above 70 $^{o}$C or sterilized by autoclaving and filtered through membrane filtration | | | |
| 6.6 | Whether alcohol or isopropyl alcohol is used as disinfectant for hand sprays? | | | |
| 6.7 | Whether disinfectant solutions filtered through membrane into suitable sterile containers before use? | | | |
| 6.8 | Whether the diluted disinfectants bear 'use before' labels based on microbiological establishment of their germicidal properties | | | |
| 6.9 | Whether records maintained thereof | | | |
| 6.10 | Whether fumigation carried out in aseptic areas. If yes, specify fumigating agent and its conc. used. | | | |
| 6.11 | Whether an SOP exist for the purpose of fumigation. | | | |
| 6.12 | Whether cleaning of sterile processing facility done using air suction devices non-linting sponges or clothes. | | | |
| 6.13 | Whether air particulate quality monitored on a regular basis | | | |
| **7.** | **Equipments** | | | |
| 7.1 | Whether the unit- sterilizers double ended with suitable inter-locking between the doors | | | |
| 7.1.1 | Whether the initial effectiveness of sterilization process established by using microbial spores indicators | | | |
| 7.1.2 | Whether thermal Mapping of heat sterilizers is carried out on regular basis. Check records. | | | |
| 7.1.3 | Whether suitable vent filters and recording thermographs provided in Autoclaves. | | | |
| 7.1.4 | Whether HEPA filters for cooling air and recording thermographs | | | |

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| | provided in DHS | | | |
| 7.1.5 | Whether provisions of CIP or SIP available. | | | |
| 7.1.6 | Whether firm has made provisions for pure steam generation and its use. | | | |
| 7.2 | *Whether filter integrity test carried out before and after the filtration process* | | | |
| 7.3 | Whether the filling machines challenged initially and there after periodically by simulation trials including sterile media fills. | | | |
| 7.4 | Are SOPs with acceptance criteria for media fills been established, validated and documented | | | |
| 7.5 | Whether the material of construction of the parts of equipment which are in direct contact with the product and the manufacturing vessels of stainless steel 316 and of glass containers Boro-silicate glass | | | |
| 7.6 | Whether the tubing used capable of washing and autoclaving | | | |
| 7.7 | Whether the installation qualification been done of all the equipments by the engineers (with the support of production and quality assurance personnel) | | | |
| 7.8 | Whether the critical processes such as aseptic filling and sterilizers suitably validated before these were put to use | | | |
| 7.9 | Whether SOPs available for each equipment for its calibration, operation and cleaning. | | | |
| 7.10 | Whether the measuring devices attached to equipment calibrated at suitable intervals. | | | |
| 7.11 | Whether a written calibration program is available | | | |
| 7.12 | Whether calibration status documented and displayed on | | | |

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| | the of the equipment and the gauges | | | |
| **8** | **Water & Steam Systems** | | | |
| 8.1 | Whether **potable water** used for the preparation of purified water meets the requirement of not more than 500 cfu/ml | | | |
| 8.2 | Whether potable water tested (100 ml sample) for freedom from pathogenic microorganisms: Escherichia coli, Salmonella, Staphylococcus aurious and Pseudomonas | | | |
| 8.3 | Whether the Purified Water prepared by de- mineralization meet the microbiological specification of not more than 100 cfu/ml | | | |
| 8.4 | Whether Purified Water tested for freedom from pathogenic microorganisms. (Sample size 100 ml) | | | |
| 8.5 | Whether Purified Water meet IP specifications for chemical testing | | | |
| 8.6 | Whether purified water is stored in stainless steel tanks. | | | |
| 8.7 | Are the distribution lines made of stainless steel 316 grades? | | | |
| 8.8 | What is the water source for preparation **Water for Injection (WFI)**: | | | |
| 8.9 | Whether WFI meet microbiological specification of not more than 10 cfu/100ml | | | |
| 8.10 | Whether WFI meet IP specifications for Water for Injection | | | |
| 8.11 | Whether WFI meet the endotoxin level of not more than 0.25 EU/ml | | | |

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| 8.12 | Whether WFI used for | | | |
| 8.12.1 | - Bulk preparations of liquid parenterals<br>- Final rinse of product containers | | | |
| 8.12.2 | - Final rinse of machine parts | | | |
| 8.12.3 | - Preparation of disinfectant solutions for use in aseptic areas | | | |
| 8.13 | Whether WFI used for liquid injectables collected freshly from the distillation plant or from a storage / circulation loop kept at above 70$^{o}$C. | | | |
| 8.14 | Whether the steam condensate meets the microbiological specification of not more than 10 cfu/100ml and IP specifications of WFI | | | |
| 8.15 | Whether steam used in production meet the endotoxin level of not more than 0.25EU/ml | | | |
| 8.16 | What is the schedule for the monitoring of steam quality exist | | | |
| **9.** | **Manufacturing process** | | | |
| 9.1 | Whether the bulk raw materials and bulk solutions monitored for bio-burden periodically (solutions not to contain more than 100 cfu/ml) | | | |
| 9.2 | Whether the principle of minimum possible time between the preparation of the solution and its sterilization or filtration through microorganism retaining filters followed and also specified in Master formula. | | | |
| 9.3 | Whether the filter the gases coming into contact with the sterile product through two 0.22 micron hydrophobic filters connected in series | | | |

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| 9.4 | Whether gas cylinders are kept out side of the aseptic areas | | | |
| 9.5 | Whether the washed containers sterilized immediately before use | | | |
| 9.6 | Whether the sterilized containers not used within an established time, rinsed with distilled or filtered purified water and re-sterilized | | | |
| 9.7 | Is each lot of the finished product filled in one continuation operation | | | |
| **10.** | **Terminally Sterilized product** | | | |
| 10.1 | Whether the preparation of Primary packaging material such as glass bottles, ampoules and rubber stoppers is carried out in at least Grade D (grade C in case there is unusual risk of contamination to the product) | | | |
| 10.2 | Whether these processes used for component preparation have been validated. | | | |
| 10.3 | Whether the filling area is **of Grade A** environment with Grade C background | | | |
| 10.4 | Whether the solutions which are sterilized by filtration is prepared in Grade C environment. | | | |
| 10.5 | And if not to be filtered, whether the preparation of materials and products carried out in Grade A environment with Grade B background | | | |
| 10.6 | Whether for aseptic filling, non-fiber releasing sterilizing grade cartridge / membrane filter of nominal pore size of 0.22 micron and 0.45 micron porosity for terminally sterilized products are used. | | | |
| 10.7 | Whether a second filtration with another 0.22 micron sterilizing grade cartridge / membrane filter, | | | |

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| | performed immediately prior to filling. | | | |
| 10.8 | Whether process specifications indicate the maximum time during which a filtration system may be used (precluding microbial build-up to levels that may affect the microbiological quality of the product) | | | |
| 10.9 | Whether integrity of the sterilizing filter verified and confirmed immediately after use. If so, by which method:<br><br>Bubble Point, Diffusive Flow or<br><br>Pressure Hold Test | | | |
| | **Sterilization (Autoclaving)** | | | |
| 10.10 | Whether the sterilizing processes have been validated<br>(Dry heat, Moist heat, filtration, ETO, ionizations whichever applicable. | | | |
| 10.11 | Whether the validity of the process verified at regular intervals (at least annually) | | | |
| 10.12 | Whether records are maintained when significant changes made to the equipment and / or the product. | | | |
| 10.13 | Whether sterilizer double ended | | | |
| 10.14 | Whether the terminal sterilizer's capacity is sufficient to sterilize one batch completely at one time. If not specify controls and measures taken in lot sterilizations. | | | |
| 10.15 | Whether the monitoring of products bio-burden carried out before terminal sterilization. | | | |
| 10.16 | Whether bio-burden controlled to the specified limits in the Master Formula. | | | |

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| 10.17 | Whether biological indicators used in monitoring of sterilization. | | | |
| 10.18 | Whether the biological indicators stored and used as per manufacturers instructions. Whether quality of BI's checked by positive controls. | | | |
| 10.19 | Whether a clear means of differentiating 'sterilized' from 'unsterilized' products in place. Specify. | | | |
| 10.20 | Whether the label on the basket / tray or other carrier of product / component clearly states:<br>• Name of the material<br>• Its batch number<br>• Its sterilization status<br>Indicator (in case it has passed through sterilization process) | | | |
| 10.21 | Whether sterilization records including thermographs and sterilization monitoring slips attached with the Batch Production Record | | | |
| 10.22 | **Sterilization (By Dry Heat)** | | | |
| 10.23 | Whether the sterilization cycle recording device of suitable size and precision provided in DHS. | | | |
| 10.24 | Whether the position of temperature probes used for controlling and / or recording determined during validation and (where applicable) been checked against a second independent temperature probe located in the same position | | | |
| 10.25 | Whether the chart forms a part of the batch record. | | | |
| 10.26 | Whether sterilization cycle validated only by biological indicator and chemical indicators or physical validation is also carried out. | | | |

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| 10.27 | Whether the time allowed reaching the required temperature before commencing the measurement of sterilizing time, separately determined for each type of load. | | | |
| 10.28 | Are adequate precautions taken to protect the load during cooling after it has gone through the high temperature phase of a heat sterilization cycle | | | |
| 10.29 | *In case the cooling is affected with any fluid or gas in contact with the product , is it sterilized.* | | | |
| 10.30 | Whether the equipment air inlet and outlets been provided with bacteria retaining filters | | | |
| 10.31 | In the process of sterilization by dry heat, does the equipment has:<br>• Air circulation facility within the chambers<br>• Positive pressure to prevent entry of non-sterile air | | | |
| 10.32 | Whether the process of dry heat sterilization is also intended to remove the pyrogens<br>If so, has the validation been done with challenge tests using endo-toxins | | | |
| 10.33 | **Sterilization (By Moist Heat)** | | | |
| 10.34 | Whether recording of both temperature and pressure carried out to monitor the process | | | |
| 10.35 | Whether the control instrumentation independent of the monitoring instrumentation and recording charts. | | | |
| 10.36 | Whether the equipment has automated control and monitoring system, if so, have | | | |

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| | these been validated to ensure that critical process requirements are met. | | | |
| 10.37 | Whether the system and cycle faults are recorded inbuilt and also observed by the operator and record maintained. | | | |
| 10.38 | *Whether the readings of the thermograph during sterilization cycling are routinely checked by the operator against the reading shown by the dial thermometer fitted with autoclave.* | | | |
| 10.39 | *Whether the sterilizer fitted with a drain at the bottom of the chamber*<br><br>*If so, does the record of temperature at this position is recorded through out the sterilizing period* | | | |
| 10.40 | Are frequent leak tests conducted on the chamber of the autoclave on each day of operation. | | | |
| 10.41 | Whether all items to be sterilized (other than sealed containers) are wrapped for sterilization. | | | |
| 10.42 | Whether the wrapping material allows removal of air and penetration of steam ensuring contact with the sterilizing agent at the required temperature for required time | | | |
| 10.43 | Whether the wrapping prevent contamination after sterilization | | | |
| 10.44 | Whether the steam used for sterilization is of suitable quality and doesn't contain additives at a level which could cause contamination of the product or equipment | | | |
| 10.45 | Whether the minimum time for all unit operations and processes are specified in the manufacture | | | |

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| | of a batch | | | |
| 10.46 | Whether the shortest validated time being adhered from the start of a batch to its ultimate release for distribution | | | |
| 10.47 | Whether the containers closing methods been validated | | | |
| 10.48 | Whether the containers closed by fusion e.g. glass or plastic ampoules, subjected to 100% leak testing | | | |
| 10.49 | Whether the samples of other containers checked for integrity as per appropriate procedures | | | |
| 10.50 | Whether the containers sealed under vacuum checked for required vacuum conditions | | | |
| 10.51 | Whether the filled containers of parenterals inspected individually for extraneous contamination /other defects | | | |
| 10.52 | Whether the inspection process done visually, if so, are the illumination and background conditions controlled. | | | |
| 10.53 | Whether the workers engaged in inspection activity pass the regular eye- sight test (with spectacles if worn) | | | |
| 10.54 | Whether the visual inspectors allowed frequent rest from inspection | | | |
| 10.55 | If other method of inspection of containers is used, | | | |
| | • What is the method- | | | |
| | • Has it been validated | | | |
| | • Are the equipment used for the purpose checked at suitable intervals | | | |
| | • Are the results/ recorded maintained | | | |
| **11.** | **Product Containers & Closures** | | | |

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| 11.1 | Whether the containers and closures used comply to pharmacopoeia or other specific requirements | | | |
| 11.2 | To assure suitability of the containers/ closures and other component parts of drug packages, whether they have:<br><br>Suitable sample sizes, Specifications, Test methods, Cleaning procedures, Sterilizing procedures | | | |
| 11.3 | Whether the container is compatible with the product and affecting its quality and purity. | | | |
| 11.4 | Whether second hand containers and closures used | | | |
| 11.5 | Whether the plastic granules used checked for fulfillment of Pharmacopoeia requirements including physico- chemical and biological tests | | | |
| 11.6 | Whether containers and the closures rinsed with WFI before sterilization | | | |
| 11.6.1 | Whether a written procedure exist for washing process. Do they follow the written schedule for cleaning of the glass bottles | | | |
| 11.6.2 | Whether the design of closures and containers suitable to make cleaning easy, and to make an air tight seal when fitted to the bottles | | | |
| 11.6.3 | Whether the material quality of the stoppers and closures ensures that it does not affect the quality of the product and avoids the risk of toxicity | | | |
| 11.6.4 | In case the bottles are not dried after washing are these rinsed with distilled water or pyrogen | | | |

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| | free water as the case may be as per written procedure | | | |
| **12.** | **Documentation** | | | |
| 12.1 | Do the manufacturing records pertaining to manufacture of sterile products indicate the following details: | | | |
| (1) | Serial number of Batch Manufacturing Record | | | |
| (2) | Name of the product | | | |
| (3) | Reference to Master Formula Record | | | |
| (4) | Batch/ Lot number | | | |
| (5) | Batch/ Lot size | | | |
| (6) | Date of commencement and completion of manufacture | | | |
| (7) | Date of manufacture and assigned date of expiry | | | |
| (8) | Date of each step in manufacturing | | | |
| (9) | Names of all ingredients with grade given by the quality control department | | | |
| (!0) | Quantity of all ingredients | | | |
| (11) | Control reference numbers for all ingredients | | | |
| (12) | Time and duration of blending, mixing etc. where ever applicable | | | |
| (!3) | PH of solutions whenever applicable | | | |
| (14) | Filter integrity testing records | | | |
| (15) | Temperature and humidity records whenever applicable | | | |
| (!6) | Records of plate-counts whenever applicable | | | |
| (17) | Results of pyrogen and/ or bacterial endotoxin and toxicity | | | |
| (18) | Records of weight or volume of drug filled in containers | | | |

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| (19) | Bulk sterility in case of aseptically filled products | | | |
| (20) | Leak test records | | | |
| (21) | Inspection records | | | |
| (22) | Sterilization records including leakage test records, load details, date, duration, temperature, pressure etc. | | | |
| (23) | Container washing records | | | |
| (24) | Total number of containers filled | | | |
| (25) | Total number of containers rejected at each stage | | | |
| (26) | Theoretical yield, permissible yield, actual yield and variation there of | | | |
| (27) | Clarification for variation in yield beyond permissible yield | | | |
| (28) | Reference number of relevant analytical reports | | | |
| (29) | Details of re-processing, if any | | | |
| (30) | Names of all operators carrying out different activities | | | |
| (31) | Environmental monitoring records | | | |
| (32) | Specimens of different packaging material | | | |
| (33) | Records of destruction of rejected containers and packaging material | | | |
| (34) | Signature of the competent technical staff responsible for manufacture and testing | | | |
| **13.** | **Notes** | | | |
| 13.1 | Whether products released only after complete filling and testing. | | | |
| 13.2 | *Whether result of the tests relating to sterility, pyrogens and bacterial endotoxins are maintained in the analytical* | | | |

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| | *records* | | | |
| 13.3 | Whether Validation details and simulation trial records maintained separately | | | |
| 13.4 | *Whether records of environmental monitoring like temperature, humidity, microbiological data etc., are maintained.* | | | |
| 13.5 | *Whether records of periodic servicing of HEPA filters, sterilizers and other periodic maintenance of facilities and equipment carried out, are maintained.* | | | |

## Checklist

| | **Part-IB**<br>**Specific Requirements for manufacture of Oral Solid Dosage Forms (Tablets and Capsules)** | **Self appraisal to be filled by the manufacturer along with all details (yes or no type reply will not be acceptable)** | **Observations to be noted by the inspecting team at the time of inspection** | **Rating to be made by the inspecting team as per Bench marks** |
|---|---|---|---|---|
| 1.1 | Please specify HVAC and air extraction systems provided to avoid contamination from extraneous particles / dust and other products.<br>Whether HVAC and air extraction system is capable of preventing discharging contaminants into the environment? In case of re-circulation of air what is the micron size of final filter. | | | |
| 1.1.1 | Are there manometers to monitor pressure differential at all strategic points. | | | |
| 1.1.2 | Is there schematic drawing of AHU's available. | | | |
| 1.1.3 | Whether dedicated AHU's for different operations are in place. | | | |
| 1.2 | Please specify how specific product requirements like temperature, humidity and light are controlled. | | | |
| 1.3 | Pls specify the materials of construction of equipments. | | | |
| 1.3.1 | Whether metal detector is used to detect metallic contamination. | | | |
| 1.4 | Whether dedicated areas for sifting provided. | | | |
| 1.5 | Pls give brief account on pressure cascade (differential pressure) being maintained in the various areas of production. | | | |

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| 1.5.1 | Whether pressure balancing is automatic or manual. | | | |
| 1.5.2 | Whether records of these pressure differential reviewed at regular interval. If yes pls specify intervals of monitoring and its review. | | | |
| 1.6 | Is Air blowing or vacuum system is used for clearing of powders from the machine parts etc. | | | |
| 1.6.1 | In case of vacuum cleaning how it is used to avoid contamination and cross contamination. | | | |
| 2 | ***SIFTING, MIXING AND GRANULATION: -*** | | | |
| 2.1 | Whether mixing, sifting and blending operations are carried out in dedicated areas & how generation of dust is controlled. | | | |
| 2.1.1 | Whether these operations are closed. | | | |
| 2.1.2 | Whether integrity of screens checked before and after operation. | | | |
| 2.1.3 | Whether mixing and blending equipment have timers for control. | | | |
| 2.2 | Whether personnel in production carry out the verification of the weight of the raw materials used in the manufacturing of each lot. | | | |
| 2.2.1 | Whether critical operating parameter likes time and temperature for each mixing and drying operation are recorded in BPR and tally with the master formula. | | | |
| 2.2.2 | Whether static or fluid bed dryers are used for drying. | | | |
| 2.2.3 | Whether FBD and static dryers have arrangements for temperature monitoring and recording. | | | |
| 2.4 | Specify the system of using filter bags used in FBD. | | | |

| | | | | |
|---|---|---|---|---|
| 2.4.1 | How filter bags are identified for various products and stored. | | | |
| 2.4.1 | Whether air entering into the dryers is filtered. If yes then specify type of filters installed. | | | |
| 2.4.2 | Whether air going out of FBD is also filtered. If yes then specify type of filters installed. | | | |
| 2.5 | Whether granulation and coating solutions are made, stored and used in a manner which minimizes the risk of contamination or microbial growth. | | | |
| 2.5.1 | Whether the washing facility in the granulation suites takes proper measures to prevent contamination and cross contamination. | | | |
| 3 | ***COMPRESSION (TABLETS)*** | | | |
| 3.1 | Whether each compression machine is installed in separate cubicle. | | | |
| | What type of dust control facilities are provided with the Tablet compressing machine in its cubicle. | | | |
| 3.2 | How granules and compressed tables stored and controlled to prevent mix ups. | | | |
| 3.2.1 | How these containers are cleaned and maintained in a proper condition. | | | |
| 3.3 | How tablets are being inspected and checked for suitable pharmacopoeial parameters like appearance, weight variation, disintegration, hardness, friability, thickness and records maintained thereof. | | | |
| 3.4 | Whether instruments used in IPQC lab are calibrated and | | | |

| | | | | |
|---|---|---|---|---|
| | accurate to measure out of specification units. | | | |
| 3.5 | How tablets are being de-dusted and monitored for the presence of foreign materials. | | | |
| 3.7 | Whether rejected or discarded tablets are isolated in identified container and their quantity recorded in the BMR. | | | |
| 3.8 | Which type of lubricating oil is used in compression machine. | | | |
| 4 | ***COATING (TABLETS):-*** | | | |
| 4.1 | Which type of tablet coaters are provided for coating. | | | |
| | Whether air supplied to coating pan is filtered. If yes pls specify type of filter and justification for its suitability. | | | |
| | Whether coating area is provided with suitable exhaust system and environmental control (temperature, Humidity) measures. | | | |
| 4.2 | Whether coating solutions are being made afresh and used. | | | |
| 5. | Filling of Hard Gelatin Capsule: - | | | |
| 5.1 | How empty gelatin capsules are stored and controlled in the filling area. | | | |
| 5.1.1 | Whether capsule filling is carried out manually or by machine. | | | |
| 5.1.2 | Whether additional provisions in the AHU's has been made to control humidity. If yes, pleases specify the same. | | | |
| 6. | Printing (tablets and capsules): - | | | |
| 6.1 | Whether the tablets / capsules are overprinted. If yes which type of ink is used. Please specify | | | |

| | | | | |
|---|---|---|---|---|
| | quality of ink. | | | |
| 6.1.1 | How printing operation is controlled to avoid mix up of products during printing. | | | |
| 6.1.2 | Whether after printing, the products are approved by quality control before release for packaging or sale. | | | |
| 7 | ***PACKAGING (STRIP & BLISTER)*** | | | |
| 7.1 | Whether a system of line clearance is in place and recorded before a new packaging operation is commenced. | | | |
| 7.2 | How contamination and cross contamination are prevented during packaging operation of tablets / capsules. | | | |
| 7.3 | How the strips/Blister coming out of the machines is inspected for defects such as miss-print, cuts on the foil, missing tablets and improper sealing. | | | |
| 7.4 | Whether IPQC tests are performed on strips or blisters? Whether records of these tests maintained. | | | |
| | | | | |

## Checklist

| | PART-IC<br>**Specific Requirements for manufacture of Oral Liquid** | Self appraisal to be filled by the manufacturer along with all details (yes or no type reply will not be acceptable) | Observations to be noted by the inspecting team at the time of inspection | Rating to be made by the inspecting team as per Benchmarks |
|---|---|---|---|---|
| | ***BUILDING AND EQUIPMENTS:*** | | | |
| **1.1**<br><br>**1.1.1** | How the facility for liquid oral designed and constructed to prevent cross contamination and mix-ups. | | | |
| | Whether the manufacturing area have entrance through double air lock facility. | | | |
| **1.1.2** | Whether in the manufacturing area walls, floors and ceiling are impervious, non-shedding, non-cracking, coved at all junctions. | | | |
| | **Whether the doors and windows and light fixtures are flushed, made up of non fiber shedding material.** | | | |
| **1.2** | Whether fly catcher and/or air carton has been provided at strategic suitable points. | | | |
| **1.3** | Whether the drains are provided with traps to prevent back flow. | | | |
| | How drains are maintained. | | | |
| **1.4** | Whether the production area is cleaned and sanitized at the end of every production process. If yes, whether records maintained.<br>(How the area is sanitized.<br>How sanitization procedures controlled). | | | |

| | | | | |
|---|---|---|---|---|
| **1.5, 1.6 & 1.8** | What is the material of construction of tanks, containers, Pipe work and pumps? | | | |
| | Whether the tanks have clean in place facility. If not how tanks are cleaned to prevent accumulation of residual microbial growth and cross-contamination. | | | |
| | How tanks, pipe works and other containers sanitized**.** | | | |
| | **Whether the pipelines and services have any dust lodging surface.** | | | |
| | Whether microbial monitoring of the area is carried out. | | | |
| | Whether use of glass containers is restricted. | | | |
| | Whether furniture's are of stainless steel and are capable of cleaned effectively. | | | |
| **1.7** | Whether cleaning of bottles, caps, droppers etc are carried out by suitable machine/devices equipped with high pressure air, water and steam jets. | | | |
| **2** | ***PURIFIED WATER: -*** | | | |
| **2.1** | Whether the Microbial quality of purified water is monitored routinely.<br>(What is the in house limit of CFU / ml of purified water). | | | |
| | Whether water is tested for freedom from Pathogen on daily basis. If not what is the schedule. | | | |
| **2.2** | Whether the unit has written procedure for operation and maintenance of purified water system. (Specify the method). | | | |

| | | | | |
|---|---|---|---|---|
| **3** | ***MANUFACTURING: -*** | | | |
| **3.1**<br>**3.2** | What types of clothing's are worn by personnel in manufacturing area? | | | |
| | Whether materials like gunny bags, or wooden pallets are allowed in manufacturing areas. | | | |
| **3.3** | Whether suspensions and emulsions are manufactured. If yes how homogeneity of the same is ensured throughout the process. | | | |
| **3.4** | Whether separate syrup preparation area has been provided,` | | | |
| | Specify the room temperature requirement in the manufacturing area. | | | |
| **3.5** | Whether the maximum period of storage of product in a bulk stage is validated and mentioned in MFR. | | | |

**Checklist**

| | **PART-ID**<br>(Specific Requirements for manufacture of topical products (Ointment, Creams, Lotion & Dusting Powders) | Self appraisal to be filled by the manufacturer along with all details (yes or no type reply will not be acceptable) | Observations to be noted by the inspecting team at the time of inspection | Rating to be made by the inspecting team as per Benchmarks |
|---|---|---|---|---|
| **1** | **Whether the entrance to manufacturing area is through an air lock.**<br>**Whether air lock is supplied with filtered air.** | | | |
| | **Whether insectocutor has been installed out side air lock.** | | | |
| **2 & 3** | **Whether HVAC system installed in manufacturing areas. If not how air quality is maintained.**<br>**Which filter is used for air filtration to the mfg. Area.** | | | |
| | **How temperature in the mfg. Area controlled.** | | | |
| | **How fumes, vapors if generated during the process are controlled.** | | | |
| **4 & 5** | **What is the material of construction of tanks, containers, Pipe work and pumps?** | | | |
| | **Whether the tanks have clean in place facility. If not how tanks are cleaned.**<br>**What type of transfer pumps is used. And precaution taken to protect the product from the contamination.** | | | |
| | **How tanks, pipe works and other containers sanitized.** | | | |
| **6.** | **Whether water used in the compounding is purified water IP.** | | | |

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|---|---|---|---|---|
| **7** | **Whether the powders whenever used are suitably sieved.** | | | |
| | **How contamination with metals prevented.** | | | |
| **8.** | **How heating of base like petroleum jelly is done in the vessels.**<br>**Whether melting facility is separate / dedicated to the process.** | | | |
| **9** | **Whether a separate packing section is provided for primary packaging of products.** | | | |
| | **Whether product is filled in tubes or jars.**<br>**How jars are cleaned before filling.** | | | |

## Checklist

| | Validation | Self appraisal to be filled by the manufacturer along with all details (yes or no type reply will not be acceptable) | Observations to be noted by the inspecting team at the time of inspection | Rating to be made by the inspecting team as per Bench marks |
|---|---|---|---|---|
| 1 | Is there a master plan **(Master validation plan)** covering: | | | |
| 1.1 | Resources and those responsible for its implementation. | | | |
| 1.2 | Identification of the systems and processes to be validated | | | |
| 1.3 | Documentation and standard operating procedures (SOPs), Work Instructions and Standards (applicable national and international standards) | | | |
| 1.4 | Validation list: facilities, processes (e.g. aseptic filling), products | | | |
| 1.5 | Key approval criteria | | | |
| 1.6 | Protocol format | | | |
| 1.7 | Each validation activity, including re-validation and reasonable unforeseen events (power failures, system crash and recovery, filter integrity failure.<br>Please attach validation calendar. | | | |
| 2. | Pls specify whether the critical processes validated Prospectively, retrospectively or concurrently. | | | |
| 3. | Whether validation of following performed and documented: Analytical methods, Production and assay equipment, Sterile production processes, Non-sterile production processes, Cleaning procedures, Critical support systems (purified water, water for injections, air,vapor, etc.), Facilities | | | |
| 4. | Please list reasons considered important for validation or re-validation. | | | |

| | | | | |
|---|---|---|---|---|
| 5. | In case electronic data processing systems are used, are these validated?<br>Please specify whether periodical challenge tests performed on the system to verify reliability. | | | |
| 6. | Are the validation studies performed according to pre-defined protocols?<br>Is a written report summarized, results and conclusions prepared and maintained?<br>Is the validity of the critical processes and procedures established based on a validation study? | | | |
| 7. | Are criteria established to assess the changes originating a revalidation?<br>Are trend analyses performed to assess the need to re-validate in order to assure the processes and procedures continue to obtain the desired results? | | | |
| 8 | **WATER SYSTEM PURIFIED WATER WATER FOR INJECTIONS** | | | |
| 8.1 | Please specify whether waster system qualification (IQ, OQ and PQ) has been carried out as per protocol and repots have been prepared and maintained. | | | |
| 8.2 | Whether IQ protocol include at least facility review, equipment specification vs. design, welding roughness testing on pipelines, absence of dead points / section in the pipelines, pipe and tank passivation, drawings, SOP for operations, cleaning, sanitation, maintenance and calibration of gadgets. Whether its report includes Conclusion / Summary, description of the performed assay, Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures. | | | |
| 8.3 | Whether OQ protocol include at least System production capacity (L/min), Flow type and water rate, Valve operation, Alarm system operation and Controls operation? | | | |
| 8.4 | Whether its report includes Conclusion / Summary, description of the performed assay, Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures. | | | |

| | | | | |
|---|---|---|---|---|
| 8.5 | Please specify the water whether Phase 1, Phase 2 and Phase 3 studies carried out in at PQ stages? | | | |
| 8.5.1 | Phase 1 : Whether the operations parameters, cleaning and sanitation procedures & frequencies defined.<br>Whether daily sampling records for every pretreatment point and usage point for a period of 2 to 4 weeks maintained and SOP's prepared. | | | |
| 8.5.2 | **PHASE 2** : Whether daily sampling records for every pretreatment point and usage point for a period of 4 to 5 weeks after Phase 1 maintained and reviewed. | | | |
| 8.5.3 | **PHASE 3 :** Whether weekly sampling records available of every usage point for a one-year period.<br>In the case of water for injections systems, are the daily sampling records of at least one usage point available, with all the usage points sampled weekly?<br>Whether results of these records summarized to show suitability.<br>Are there personnel training records? | | | |
| 9. | **EQUIPMENT** | | | |
| 9.1 | Are the equipment installation Qualification (IQ) protocols contains followings:<br>Introduction, Installation description, Responsibilities, Performed tests/assays, Qualification acceptance criteria and Data recording and reporting? | | | |
| | Whether report contains Summary, Description of performed tests/assays, Obtained data tables, Results, Conclusions, Installation diagrams, Revision and approval signatures. | | | |

| | | | | |
|---|---|---|---|---|
| 9.2 | Whether the equipment operation qualification (OQ) protocols contains following: Introduction, Equipment description, Description of the equipment operation steps (SOP's), Responsibilities, Qualification acceptance criteria, Data recording and reporting. Whether report contains Summary, Description of performed tests/assays, Obtained data tables, Results, Conclusions, Revision and approval signatures. | | | |
| 9.3 | Whether equipment performance qualification (PQ) protocols contains followings: Introduction, esponsibilities, Performed assays, Qualification acceptance criteria, Data recording and reporting. | | | |
| | Whether report contains Summary, Description of performed tests/assays, Obtained data tables, Results, Conclusions, Revision and approval signatures.g | | | |
| 10. | **Analytical Method Validation** | | | |
| 10.1 | Please specify whether following Characteristics are considered during validation of analytical methods:<br>— specificity<br>— linearity<br>— range<br>— accuracy<br>— precision<br>— detection limit<br>— quantitation limit<br>— Robustness. | | | |
| 10.2 | Whether Paharmocopial methods are also validated. If yes, how. | | | |
| 10.3 | Whether system suitable testing is included in testing protocols e.g. HPLC, GC etc. | | | |
| 11 | **CLEANING** | | | |

| | | | | |
|---|---|---|---|---|
| 11.1 | Is a validation performed to confirm cleaning effectiveness? | | | |
| | Does the protocol define the selection criteria for products or groups of products subject to cleaning validation? | | | |
| | Is data produced supporting the conclusion that residues were removed to an acceptable level? | | | |
| 11.2 | Please specify whether the validation is implemented to verify cleaning of:<br>Surfaces in contact with the product, After a change in product, Between shift batches. | | | |
| | Please specify whether the Validation Strategy include contamination risks, equipment storage time, the need to store equipment dry and sterilize and free of pyrogens if necessary? | | | |
| 11.3 | Whether the cleaning Validation Protocol include:<br>a. Interval between the end of production and the beginning of the cleaning SOP's.<br>b. Cleaning SOP's to be used.<br>c. Any monitoring equipment to be used.<br>d. Number of consecutive cleaning cycles performed?<br>e. Clearly defined sampling points. | | | |
| 11.4 | Whether Quality Control responsible of the sampling for cleaning verification? | | | |
| 11.5 | Whether personnel engaged in cleaning, sampling etc. trained. | | | |
| 11.6 | Please specify whether acceptance limits been set for cleaning verification and are based on following criteria:<br>a. Visually clean.<br>b. 10 ppm in another product<br>c. 0.1% of the therapeutic dose? | | | |
| 11.7 | Please specify whether detergent residues investigated and degradation products verified during validation. | | | |

| | | | | |
|---|---|---|---|---|
| 11.7.1 | Whether validation records include Recovery study data, Analytical methods including Detection Limits and Quantification Limits, Acceptance Criteria, Signatures of the Quality Assurance Manager, employee in charge of cleaning and the verification from Production and Quality Control. | | | |
| 12 | **HVAC** | | | |
| 12.1 | Please specify whether following parameters have been qualified:<br>— temperature<br>— relative humidity<br>— supply air quantities for all diffusers<br>— return air or exhaust air quantities<br>— room air change rates<br>— room pressures (pressure differentials)<br>— room airflow patterns<br>— unidirectional flow velocities<br>— containment system velocities<br>—filter penetration tests (HEPA)<br>— room particle counts<br>— room clean-up rates<br>— microbiological air and surface counts where appropriate<br>— operation of de-dusting<br>— warning/alarm systems where applicable. | | | |
| 12.2 | Whether strategic tests like Particle count, air pressure differential, air flow volume, air flow velocity etc. included in HVAC qualification. | | | |
| 13 | **Media fill test** | | | |
| 13.1 | Whether medial fill tests carried out twice in a year during normal working conditions. | | | |
| | Pls give date of last such test. | | | |
| 13.2 | How many units are filled and tested. | | | |
| | What is the criterion for qualification of this test? | | | |
| 13.3 | In case of failure of media fill test, what precautions or actions are taken. | | | |

| | **Specific Product Information** | Self appraisal to be filled by the manufacturer along with all details (yes or no type reply will not be acceptable) | Observations to be noted by the inspecting team at the time of inspection | Rating to be made by the inspecting team as per Bench marks |
|---|---|---|---|---|
| 1. | Name of product<br>(i) Generic Name<br>(ii) Brand Name<br>(iii) Dosage Form<br>(iv) Strength | | | |
| 2. | Whether validated master formula is available? | | | |
| 3. | Whether specific SOP for product processing is available? | | | |
| 4. | Comments on the above SOP | | | |
| 5. | No. of Batches Produced | | | |
| 6. | Stability studies<br>(i) Accelerated<br>(ii) Real Time<br>(iii) Whether the expiry date assigned on the basis of stability study? | | | |
| 7. | Whether trend analysis was carried out and interpretation thereof? | | | |
| 8. | Whether Annual product review (APR) is carried out? | | | |
| 9. | Is there any complaint received for the product and If any, whether the investigation report along with ATR is maintained? | | | |

## Technical Guidance Note to the Industry

1. **Quality Assurance**

1.1 Manufacturers should have a comprehensive Quality Assurance system. This should cover deviation reporting and investigation, and change control.

2. **Good Manufacturing Practices (GMP)**

2.1 The manufacturer should ensure that all manufacturing processes are clearly defined, systematically reviewed in the light of experience, and shown to be capable of consistently manufacturing pharmaceutical products of the required quality that comply with their specifications.

2.2. Manufacturers should ensure that qualification and validation are performed; all necessary resources are provided, including appropriately qualified and trained personnel; adequate premises and space; suitable equipment and services; appropriate materials, containers and labels; approved procedures and instructions; suitable storage and transport; adequate personnel, laboratories and equipment for in process controls; instructions and procedures are written in clear and unambiguous language, specifically applicable to the facilities provided; operators are trained to carry out procedures correctly; records are made (manually and/or by recording instruments) during manufacture to show that all the steps required by the defined procedures and instructions have in fact been taken and that the quantity and quality of the product are as expected; any significant deviations are fully recorded and investigated; records covering manufacture and distribution, which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form; the proper storage and distribution of the products minimizes any risk to their quality; a system is available to recall any batch of product from sale or supply; complaints about marketed products are examined, the causes of quality defects investigated, and appropriate measures taken in respect of the defective products to prevent recurrence.

3. **Sanitation**

3.1 Personnel should be instructed to wash their hands before entering production areas.

1.2. Appropriate hair covering should be worn. Used clothes, if reusable, should be stored in separate closed containers until properly laundered and, if necessary, disinfected or sterilized.

4. **Qualification and validation**

4.1.The key elements of a qualification and validation programme of a company should be clearly defined and documented in a validation master plan.

4.2. Qualification and validation should establish and provide documentary evidence that:

(a) The premises, supporting utilities, equipment and processes have been designed in accordance with the requirements for GMP (design qualification or DQ).
(b) The premises, supporting utilities and equipment have been built and installed in compliance with their design specifications (installation qualification or IQ);

(c) The premises, supporting utilities and equipment operate in accordance with their design specifications (operational qualification or OQ)
(d) A specific process will consistently produce a product meeting its predetermined specifications and quality attributes (process validation or PV, also called performance qualification or PQ)

4.3. Any aspect of operation, including significant changes to the premises, facilities, equipment or processes, which may affect the quality of the product, directly or indirectly, should be qualified and validated.

4.4. Qualification and validation should not be considered as one-off exercise. An on-going programme should follow their first implementation and should be based on an annual review.

4.5. The commitment to maintain continued validation status should be stated in the relevant company documentation, such as the quality manual or validation master plan.

4.6. Validation studies are an essential part of GMP and should be conducted in accordance with predefined and approved protocols.

4.7. A written report summarizing the results recorded and the conclusions reached should be prepared and stored.

4.8. Processes and procedures should be established on the basis of the results of the validation performed.

4.9. It is of critical importance that particular attention is paid to the validation of analytical test methods and automated systems.

**2. <u>Complaints</u>**

**3.**

5.1 Special attention should be given to establishing whether a complaint was caused because of counterfeiting.

5.2. If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected. In particular, other batches that may contain reprocessed product from the defective batch should be investigated.

5.3. Complaints records should be regularly reviewed for any indication of specific or recurring problems that require attention and might justify the recall of marketed products.

6. **Product recalls**

6.1. The authorized person should be responsible for the execution and coordination of recalls. He/she should have sufficient staff to handle all aspects of the recalls with the appropriate degree of urgency.

6.2. All licensing authorities of all states to which a given product has been distributed should be promptly informed of any intention to recall the product because it is, or is suspected of being, defective.

7. **Self-inspection and quality audits**

7.1The frequency at which self-inspections are conducted may depend on company requirements but should be at least once a year. The frequency should be stated in the procedure.

7.2. A report should be made at the completion of a self-inspection. The report should include;
(a) Self-inspection observations;
(b) Evaluation and conclusions;
(c) Recommended corrective actions.

7.3. There should be an effective follow-up programme. The company management should evaluate both the self-inspection report and the corrective actions as necessary.

7.4. There should be a system for qualification of vendor.

8. **Personnel and training**

8.1. Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.

8.2. The duties of responsible staff may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of personnel concerned with the application of GMP. The manufacturer should have an organization chart.

8.3. Key personnel include the head of production, the head of quality control and the authorized person. Normally, key posts should be occupied by full-time personnel. The heads of production and quality control should be independent of each other. In large organizations, it may be necessary to delegate some of the functions; however, the responsibility cannot be delegated.

Competent key personnel responsible for supervising the manufacture quality control and Quality Assurance of pharmaceutical products should possess the qualifications of a scientific education and practical experience required by national legislation. Their education should include the study of an appropriate combination of:

(a) Chemistry (analytical or organic) or biochemistry;
(b) Chemical engineering;
(c) Microbiology;
(d) Pharmaceutical sciences and technology;
(e) Pharmacology and toxicology;
(f) Physiology;
(g) Other related sciences.

8.5. They should also have adequate practical experience in the manufacture and quality assurance of pharmaceutical products. In order to gain such experience, a preparatory period may be required, during which they should exercise their duties under professional guidance. The scientific education and practical experience of experts should be such as to enable them to exercise independent professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and quality control or pharmaceutical products.

8.6. The heads of the production and quality control generally have some shared, or jointly exercised, responsibilities relating to quality. These may include, depending on national regulations:

(a) authorization of written procedures and other documents, including amendments;
(b) monitoring and control of the manufacturing environment;
(c) plant hygienic;
(d) process validation and calibration of analytical apparatus;
(e) training, including the application and principles of quality assurance;
(f) approval and monitoring of suppliers of materials;
(g) approval and monitoring of contract manufacturers;
(h) designation and monitoring of storage conditions for materials and products;
(i) performance and evaluation of in-process controls;
(j) retention of records;
(k) monitoring of compliance with GMP requirements;
(l) inspection, investigation and taking of samples in order to monitor factors that may affect product quality.

8.7. The head of the production generally has the following responsibilities:

(a) to ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality;

(b) to approve the instructions relating to production operations, including the in-process controls, and to ensure their strict implementation;

(c) to ensure that the production records are evaluated and signed by a designated person;

(d) to check the maintenance of the department, premises, and equipment;

(e) to ensure that the appropriate process validations and calibrations of control equipment are performed and recorded and the reports made available;

(f) to ensure that the required initial and continuing training of production personnel is carried out and adapted according to need.

8.8. The head of the quality control generally has the following responsibilities;

(a) to approve or reject starting materials, packaging materials and intermediate, bulk and finished products in relation with their specification;

(b) to evaluate batch records;

(c) to ensure that all necessary testing is carried out;

(d) to approve sampling instructions, specifications, test methods and other quality control procedures;

(e) to approve and monitor analyses carried out under contract;

(f) to check the maintenance of the department, premises and equipment;

(g) to ensure that the appropriate validations, including those of analytical procedures, and calibrations of control equipment are carried out;

(h) to ensure that the required initial and continuing training of quality control personnel is carried out and adapted according to need.

8.9. The authorized person **from Quality Assurance** is responsible for compliance with technical or regulatory requirements related to the quality of finished products and the approval of the release of the finished product for sale.

8.10. The authorized person will also be involved in other activities, including the following;

(a) implementation (and, when needed, establishment) of the quality system;
(b) participation in the development of the company's quality manual;
(c) supervision of the regular internal audits or self –inspections;
(d) oversight of the quality control department;
(e) participation in external audit (vendor audit)
(f) participation in validation programmes.

8.11. The function of the approval of the release of a finished batch or a product can be delegated to a designated person with appropriate qualifications and experience who will release the product in accordance with an approved procedure

8.12. The person responsible for approving a batch for release should always ensure that the following requirements have been met:

(a) the marketing authorization and the manufacturing authorization requirements for the product have been met for the batch concerned;

(b) the manufacturing and testing processes have been validated, if different;

(c) all the necessary checks and tests have been performed and account taken of the production conditions and manufacturing records;

(d) any planned changes or deviations in manufacturing or quality control have been notified in accordance with a well defined reporting system before any product is released.

(e) any additional sampling, inspection, tests and checks have been carried out or initiated, as appropriate, to cover planned changes and deviations;

(f) all necessary production and quality control documentation has been completed and endorsed by supervisors trained in appropriate disciplines;

(g) appropriate in process checks and spot-checks are carried out by experienced and trained staff;

(h) approval has been given by the head of quality control.

8.13. Continuing training should also be given, and its practical effectiveness periodically assessed.

8.14. Training programmes should be available. Training records should be kept.

8.15. The concept of quality assurance and all the measures which aid its understanding and implementation should be fully discussed during the training sessions.

8.16. Visitors or untrained personnel should preferably not be taken into the production and quality control areas. If this is unavoidable, they should be given relevant information in advance (particularly about personal hygiene) and the prescribed protective clothing. They should be closely supervised.

8.17. Consultant and contract staff should be qualified for the services they provide. Evidence of this should be included in the records.

9. **Premises**

9.1. Electrical supply should be appropriate and such that they do not adversely affect, directly or indirectly, either the pharmaceutical products during their manufacture and storage, or the accurate functioning of equipment.

9.2. Receiving areas should be designed and equipped to allow containers of incoming materials to be cleaned if necessary before storage.

10. **Equipment**

10.1. Washing, cleaning and drying equipment should be chosen and used so as not to be a source of contamination.

11. **Materials**

11.1. Materials dispensed for each batch of the final product should be kept together and conspicuously labeled as such.

11.2. All products and packaging materials to be used should be checked on delivery to the packaging department for quantity, identity and conformity with the packaging instructions.

11.3. The purchase of starting materials is an important operation that should involve staff who has a adequate knowledge of the products and suppliers.

**Finished Products**

11.4. Finished products should be held in quarantine until their final release, after which they should be stored as usable stock under conditions established by the manufacturer.

**12. Returned Products**

12.1. Products returned from the market should be destroyed unless it is certain that their quality is satisfactory; in such cases they may be considered for resale or relabelling, or alternative action taken only after they have been critically assessed by the quality control function in accordance with a written procedure. The nature of the product, any special storage conditions it requires, its condition and history, and the time elapsed since it was issued should all be taken into account in this assessment. Where any doubt arises over the quality of the product, it should not be considered suitable for reissue or reuse. Any action taken should be appropriately recorded.

**Reagents and culture media**

12.2. There should be records for the receipt and preparation of reagents and culture media.

12.3. Reagents made up in the laboratory should be prepared according to written procedures and appropriately labeled. The label should indicate the concentration, standardization factor, shelf-life, the date when re-standardization is due, and the storage conditions. The label should be signed and dated by the person preparing the reagent.

12.4. Both positive and negative controls should be applied to verify the suitability of culture media each time they are prepared and used. The size of the inoculum used in positive controls should be appropriate to the sensitivity required.

12.5. Reference standards prepared by the producer should be tested, released and stored in the same way as official standards. They should be kept under the responsibility of a designated person in a secure area.

12.6. Secondary or working standards may be established by the application of appropriate tests and checks at regular intervals to ensure standardization.

13. **Documentation**

13.1. The reproduction of working documents from master documents must not allow any error to be introduced through the reproduction process.

14. **Good practices in quality control**

14.1. Out-of-specification results obtained during testing of materials or products should be investigated.

14.2. Records demonstrating that all the required sampling, inspecting and testing procedures have actually been carried out and that any deviations have been fully recorded and investigated.

14.3. All tests should follow the instructions and results should be checked by the supervisor before the material or product is released.

14.4. Sampling equipment should be cleaned and if necessary, sterilized, before and after each use and stored separately.

14.5. Replace with 929 requirements.

14.6. Quality control should evaluate the quality and stability of finished pharmaceutical products and, when necessary, of starting materials and intermediate products.

14.7. A written programme for ongoing stability determination should be developed and implemented.

14.8. Stability should be determined prior to marketing and following any significant changes in processes, equipment, packaging materials.

## *22. Check List*

**(All the pages of the bid should be Serial Numbered & signed/initialled)**

| Sl. No. | | Activity | Yes/No/ NA | Page No. in the Bid |
|---|---|---|---|---|
| 1 | (a) | **Bid Security** for required amount | | |
| | (b) | Bid Security in the form of | | |
| | *(i)* | *Bank Guarantee as per format in Bidding document* | | |
| | *(ii)* | *Draft or Banker's cheque issued by Nationalised bank* | | |
| | (c) | Validity Date of Bid Security (**Valid upto28-days beyond the bids validity) as specified in ITB Data Sheet clause19.2**) | | |
| | (d) | Amendment in Bid Security ( if any) | | |
| 2 | | **The Bank details from where the Bank Guarantee has been issued along with Phone, fax numbers and email Ids. For Banks from outside India the details of the correspondent Bank in India.** | | |
| 3 | (a) | **Bid Form** duly signed | | |
| | (b) | **Power of Attorney** in favour of the signatory | | |
| 4 | (a) | **Availing Deemed Export benefits?** | | |
| | (b) | **Form of Declaration regarding Deemed Export** | | |
| 5 | | The **manufacturer's authorization** form in Form 8 of Section VIII. | | |
| 6 | | **Documents establishing post qualification (ITB 7.1(a))** | | |
| (a) | | **Certificate of incorporation** of Manufacturer | | |
| (b) | | **Manufacturing Licence** of the good(s) quoted in bid | | |
| (c) | | **Proof of Exp in manufacturing & marketing of specific goods** for at least 1(one) years, Indicate Serial No. in performance statement | | |
| (d) | | **Proof of experience in manufacturing & marketing of similar goods** for at least 3 years, Indicate Serial Nos in performance statement | | |
| (e) | | Performance statement as per required Proforma, along with **supporting documents viz. (i) Copy of Purchase Orders,(ii) Copy of Invoices, (iii) Proof of Payment received from Purchasers & (iv) Documentary evidence (Client's certificate) in support of satisfactory completion of** | | |

| Sl. No. | | Activity | Yes/No/ NA | Page No. in the Bid |
|---|---|---|---|---|
| | | **contract.** | | |
| (f) | | **WHO GMP** valid on the date of opening of bid | | |
| (g) | | **COPP Certificates** of the specific item, valid on the date of opening of Bid. | | |
| (h) | | Indicate Sr. No. in **performance statement** which establishes the post qualification criteria of completing one similar contract in last five years | | |
| (i) | | Certificate of having **achieved Annual production** rate of equivalent product for last three years by CA | | |
| (j) | | Copies **complete set of audited financial statements** of accounts (including balance sheet, profit and loss account, auditor's reports and IT returns) certified by the auditor of the Company for last three financial years | | |
| 7 | | Documents to establish that **product is registered in India** as per ITB clause 6.4 if applicable | | |
| 8 | | Details of **onsite quality control laboratory facilities and services and range of test conducted.** | | |
| 9 | | **Capacity and Quality certification form** in the format provided in Bidding document **issued by relevant Country Authority**. | | |
| 10 | | **Manufacturing Authorization Certificate (if applicable)** | | |
| 11 | | **Statement of installed manufacturing capacity c**ertified by appropriate authority | | |
| 12 | | **No deviation statement on technical specification** | | |
| 13 | | **Check list of technical specification** | | |
| 14 | (a) | **Agreement with all terms and condition of the bid document** | | |
| | (b) | If no, have you indicated deviations | | |
| 15 | (a) | **Mentioned Price in the appropriate Proforma** | | |
| | (b) | **Conditional or unconditional discount** mentioned in the bid (if any) | | |
| 16 | | Copies of original documents defining the constitution or **legal status, place of registration, and principal place of business; for both manufacturer & non manufacturer** | | |

| Sl. No. | | Activity | Yes/No/ NA | Page No. in the Bid |
|---|---|---|---|---|
| 17 | | **Undertaking** as per clause ITB 7.1(a) {The **bidder** and the **manufacturer** whose product is offered by the bidder shall disclose instance of previous past performance of his and the manufacturer whose product is procured by the bidder, that may have resulted into adverse actions taken against the bidder during the last two years. Such adverse actions taken against the bidder or manufacturer may be treated as unsatisfactory performance history while deciding the award of contract. **If no adverse action has been taken against the Bidder, the Bidder must provide a statement in its** bid saying that there has been no such previous past performance resulting in adverse actions being taken against him.} | | |
| 18 | (a) | The bidder shall provide an **undertaking** that:<br>The **proprietor/promoter/director of the firm, its employee, partner or representative is not convicted by a court of law** following prosecution for offence involving moral turpitude in relation to business dealings including malpractices such as bribery, corruption, fraud, substitution of bids, interpolation, misrepresentation, evasion, or habitual default in payment of tax levied by law; etc. | | |
| | (b) | The firm **does not employ a government servant, who has been dismissed or removed on account of corruption**. | | |
| 19 | | Form 11: Proforma for other details of Bidder, Manufacturer and its Bank | | |