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Ref. No.: F.02(191)/RMSC/PROCUREMENT/DRUG/NIB-10/2016/987 Dated: 26-07-2016

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.

(A Govt. of Rajasthan Undertaking)
Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India
Tel No: 0141-2228066, 2228064, E-mail: rmsc@nic.in,
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E-BID FOR RATE CONTRACT CUM SUPPLY AND EMPANELMENT OF DRUGS AND MEDICINES
(Two year Rate Contract ending on 30.09.2018)

!! सर्वे सन्तु निरामयाः!!

LAST DATE OF SUBMISSION OF ONLINE BIDS:- 30.08.2016

Ministry of Health & Family Welfare
Government of Rajasthan
RMSCL
"Mukhyamantri Nishulak DavaYojana"
Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India
Phone No: 0141-2228066 , 2228064 Fax No. 0141-2228065 Website: www.rmsc.nic.in
CIN:U24232RJ2011SGC035067 E_mail : edprocurement@gmail.com, and rmsc@nic.in

Ref. No.: F.02(191)/RMSC/PROCUREMENT/DRUG/NIB -10/2016/987 Dated: 26-07-2016

Notice Inviting E-Bids

E-bids are invited upto 1.30 PM of 30.08.2016 for Rate Contract cum Supply and Empanelment of drug and medicines. Details of NIB may be seen in the Bidding Documents at our office or at the website of State Public procurement Portal http://sppp.raj.nic.in, www.dipronline.org, http://eproc.rajasthan.gov.in., www.rmsc.nic.in and may be downloaded from there.

Note:- If any amendment is carried out in the tender specifications and terms & conditions following pre-bid meeting, the same will be uploaded on the Departmental website www.rmsc.nic.in, sppp.raj.nic.in and https:// eproc.rajasthan.gov.in. In case any inconvenience is felt, please contact on telephone number i.e. 0141- 2228064

Executive Director (Procurement)
RMSCL

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
RAJASTHAN

E-BID FOR RATE CONTRACT CUM SUPPLY AND EMPANELMENT OF DRUGS AND MEDICINES
(Two year Rate Contract ending on 30.09.2018)

Bid Reference	:	F.02(191)/RMSC/PROCUREMENT/DRUG/ NIB-10/2016/987 Dated:26.07.2016
Pre- bid conference	:	**03.08.2016 at 11.30 AM** (RMSC meeting Hall)
Date and time for downloading bid document	:	**28.07.2016 from 05.00 PM**
Last date and time of submission of online bids and e-deposit	:	**30.08.2016 at 1.30 PM**
Date and time of opening of Online technical bids	:	**30.08.2016 at 2.30PM**
Cost of the Bid Document	:	**Rs. 2000/-**
For SSI Unit of Rajasthan	:	**Rs. 1000/-**
RISL Processing Fees	:	**Rs. 1000/-**
Empanelment Fee (If applying for Empanelment also)	:	**Rs. 5000/-**

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GENERAL INSTRUCTIONS FOR BIDDERS

The bidders are instructed to read the complete bid document carefully. The following points may be noted so that mistakes/lapses/shortcomings during Bid submission may be avoided.

1. ***It is expected from all bidders that they will ensure that documents to be used in bid set will be given to a reliable person only, and that only a fully reliable person shall be authorized for DSC. So that the confidentiality of your bid/ rates is maintained upto bid opening & that your documents are not put to any misuse.***
2. ***Complaints lodged in RMSC should bear signature, name, Id proof and mobile number of the complainant. This is important as RMSC has received many complaints in the past on letter heads of certain companies who later on denied to have made the complaint upon their verification. Rather, a few companies have asked RMSC to take action against those persons who have fraudulently made use of their letter heads. Therefore, unauthenticated complaints may not be acted upon.***
3. ***In case you are given any assurance of any favour in RMSC, by anybody or if you are directly or indirectly threatened or intimidated of harming your bidding & subsequent work in RMSC, please inform immediately about the same to MD, RMSC or ED(Proc.) RMSC. It would be better if evidence of such unfair activity of such person is produced so that action can be taken against such person / institution and their details can be put on the website.***
4. ***It is advisable for you to authorize only those persons for RMSC tender who are employed in your company on salary basis.***
5. ***If any firm, etc intends to lodge a complaint against a bidder with regard to bid (bid Condition), it may do so within 21 days of opening of technical bid, in the office of RMSC. After the stipulated period, it will not be possible to act upon the complaint.***
6. The turnover should be as per bid conditions. Do not submit Bid if the turnover of the firm is less.
7. Quote only for the products for which your Product Permission meets the Bid specifications. Do not quote if it differs with regard to any parameter.
8. Quote rate in BOQ for the packing exactly given in annexure VIII. For example

- If the packing unit is given for 10x10 tablets / capsule, the rate should be quoted for 10x10 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.
- If the packing unit is given for 10x10x1 tablets / capsule, the rate should be quoted for 10x10 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.
- If the packing unit is given for 10x14 tablets / capsule, the rate should be quoted for 10x14 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.
- If the packing unit is given for 2 ml ampoule (25 ampoules), the rate should be for 25 ampoules and not for 1 ampoule or 10 ampoules etc.
- If the packing unit is given for 2 ml ampoule (10 ampoules), the rate should be for 10 ampoules and not for 1 ampoule etc.

9. Highlight the quoted items in the documents like Product Permission and Market Standing Certificate, and also mark the item code no. at appropriate place in the documents.
10. The uploaded product permission and other documents should be clearly legible. Date of issue of the documents should be clearly legible.
11. Upload the Bids on the e-portal well in advance so that failure in uploading can be avoided and no desired document remains un-uploaded.
12. In case there is any suggestion regarding Bid conditions/specifications/shelf life, strength, packing/turn over etc. The suggestions should be submitted/sent/E – Mailed one/two days earlier from the date of pre bid meeting so that the representation of the bidders may be well processed and decision could be taken well in time.
13. If there is any query regarding Terms and condition in Bid document, you may contact

    Sh. Deepak Sharma, Sr. Manager (Drugs) Mob. No. 08875298700

    Sh. K.K. Moolchandani, Manager (Procurement) Mob. No. 09460764250

RAJASTHAN MEDICAL SERVICES CORPORATION LTD. RAJASTHAN

E-BID FOR RATE CONTRACT CUM SUPPLY AND EMPANELMENT OF DRUGS AND MEDICINES
(Two year Rate Contract ending on 30.09.2018)

Rajasthan Medical Services Corporation Ltd., (hereinafter referred to as Bids Inviting Authority unless the context otherwise requires) invites E-BID FOR RATE CONTRACT CUM SUPPLY AND EMPANELMENT OF DRUGS AND MEDICINES.

1. **LAST DATE FOR RECEIPT OF BIDS, BID DOCUMENT FEES, BID SECURITY DEPOSIT, RISL PROCESSING FEES AND EMPANELMENT FEES**

(a) E-Bids [in two separate bids (Technical bid & Price Bid)] will be received till 30.08.2016 at 1.30 PM by the Rajasthan Medical Services Corporation Ltd, for the rate contract cum supply and empanelment for supply of drugs and medicines. (Two year Rate Contract ending on 30.09.2018)

(b) The bids shall be valid for a Period of 120 days from the date of opening of Technical Bid and prior to the expiration of the bid validity the Bid Inviting Authority may request the Bidders to extend the bid validity period for an additional specified period of time. The Bidder may refuse extension of bid validity, and in such a case its Bid security deposit shall not be forfeited.

(c) The e-Bids will be received on e-procurement web-portal of Govt. of Rajasthan. Every Bidder will be required to pay the following fees:

- Bid form fee Rs. 2000.00 (Rs. 1000.00 for SSI Units of Rajasthan) for downloading from the website.
- Bid Security Deposit as applicable in Bid condition no. 8.
- Processing fee of Rs.1000.00 of R.I.S.L.

These fees are to be paid through three separate prescribed challans (***format enclosed in Annexure- I)*** in any branch of the Punjab National Bank Account no. 2246002100024414 throughout country upto 29.08.2016 or through D.D. / bankers cheque in favour of M.D. RMSCL (Bid document

fees and Bid security), M.D. RISL (Bid processing fees) physically in the office of RMSC by 1.30 PM on 30.08.2016 ***Alternatively bidder may also deposit Bid document fees, Bid security and RISL processing fees by way of e-deposit, through Internet Banking by accessing RMSC website rmsc.nic.in clicking e-deposit icon following the laid down steps; Rs.25 plus applicable service tax will be the per transaction charge to be debited in respective depositor's account after successful e-deposit. Supplier should enclose the generated receipt***. The bidders shall submit/upload scanned copy of all the challans/DD/ ***e – deposit generated receipt*** in Technical Bid**.** Bids will be opened only after ensuring receipt of Bid document fees along with processing fees and Bid Security Deposit. In the absence of Bid document fees and processing fees and Bid Security Deposit the Bids will be rejected and will not be opened.

Note:- (I) ***While the Bid uploading it would be asked on e procurement website about Bid Security, whether it is Rs. 2.00 lacs or Rs. 5.00 lacs , the bidder may mention any option for the purpose of Bid uploading but has to submit required Bid Security as specified in clause no 8.***

Note:- (II) ***There is no option of online payment of tender fee, processing fee, bid security etc. on e-procurement portal. Therefore the bidder is advised to submit the required fees and bid security through internet banking only by accessing RMSC website www.rmsc.nic.in.***

Click on offline mode (either DD or BC) on e procurement portal for the purpose of bid uploading only.

(d) Those who wish to apply for Empanelment as supplier for Drugs and Medicines are required to deposit separately an Empanelment Fee of Rs 5000 (Five Thousand rupees only) in the form of DD (in favour of MD, RMSCL)/challan/e-deposit before due time and date of bid submission. Please see clause 20 and Annexure-XI in this regard.

Note:-The bidders who have already paid empanelment fees in previous bid need not to submit the empanelment fee for the items being quoted in this bid. However the required annexure must be submitted.

2. ELIGIBILITY CRITERIA

(a) Bidder shall be a manufacturer having valid manufacturing license or direct importer holding valid import license. Distributors/ Suppliers / Agents are not eligible to participate in the Bids.

(b) Average Annual turnover (for drugs and medicines including Surgical and sutures Business) in the last three financial years (2012-13, 2013-14 and 2014-15 or 2013-14, 2014-15 and 2015-16) shall not be less than Rs. 20 Crores. For SSI units of Rajasthan, the average annual turnover in the last three financial years (2012-13, 2013-14 and 2014-15 or 2013-14, 2014-15 and 2015-16) should not be less than Rs. 2 Crores. For drug items (item code 244, 252, 320, 326, 424, 425 and 612) falling in the category of Disinfectants & Antiseptics, Eye preparations and Ear drops etc and item - *Treponemal-specific Rapid (Point-of- Care) Diagnostic Test for Syphilisthe,* bidders firm*s* average annual turnover of last three financial years should not be less than Rs. 2 Cr.

Explanatory Note:-

1) **The merger / amalgamation / transfer of business / transfer of assets / share in sister concern / share in joint venture etc. of a firm affect the bid condition relating to 'Turnover' in preceding years. The eligibility of a bidder in this regard shall be ascertained by the Purchase Committee on the basis of the above stated agreement / BOD resolution / CA certificate or any other document(s) annexed with the tender documents and the decision of Purchase Committee shall be final.**
2) **The amount shown as Turnover in the tender should be the amount as per VAT Act / other Acts and necessary documents / certificates shall be annexed with tender documents and accordingly eligibility of a bidder in this regard shall be ascertained by the Purchase Committee**.

(c) Bidder should have at least 3 years market standing as a manufacturer for the items quoted in the bid, on the date of bid opening. ***The bidder should also have manufactured at least 3 commercial batches of the quoted drug every year in the last 3 consecutive years (Annexure XV)***. In the case of imported products, the product should have minimum 3 years standing in the market. The importer should have at least 3 years standing as manufacturer/ importer of drugs in general. Imported drugs shall be accepted in brand name also.

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Explanatory Note:

The merger / amalgamation / transfer of business / transfer of assets / share in sister concern / share in joint venture etc. of a firm affect the bid condition relating to 'Past Performance' / 'Market Standing Certificate' in preceding years. The eligibility of a bidder in this regard shall be ascertained by the Purchase Committee on the basis of the above stated agreement / BOD resolution / CA certificate or any other document(s) / certificates which shall be annexed with the tender documents.

(d) Bidder should have permission to manufacture the item /drug quoted as per specification given in the Bid, from the competent authority. Product permission of *brands* shall be accepted in the Bid submitted, but the Bidder has to submit the product permission in generic names at the time of signing of the agreement/before supply.

(e) Bid should not be submitted for the product/products for which the concern/company stands blacklisted/banned/debarred either by Bid inviting Authority or Govt. of Rajasthan or its departments on any ground.

The Bid should not be submitted for those products also for which the concern/company stands blacklisted/banned/debarred by any other State/Central Govt. or it's any agencies (central Drugs procurement agencies) on the ground of conviction by court of law or the products being found spurious or adulterated.

(f) The concern/company/firm which stands blacklisted/banned/debarred on any ground either by Bid Inviting Authority (RMSC) or Govt. of Rajasthan or its departments on the date of bid submission, shall not be eligible to participate in the Bid.

The concern/company/firm which stands blacklisted/banned/debarred on the ground of conviction by court of law or the products being found spurious or adulterated by any other State /Central Government or it's any agencies (central Drugs procurement agencies) shall also not be eligible to participate in the Bid. For Specific cases regarding other quality issues the purchase committee of RMSC may decide the case on merit basis.

(g) If any product/products of a company/firm have been declared as not of standard quality, as per Drugs & Cosmetics Act during last 2 years anywhere, such concern/company/firm shall not be eligible to participate in Bid for such

product/products. If any company/firm is found to have any such product quoted in the Bid, the product shall be blacklisted for 2 years and a penalty equivalent to Bid Security Deposit shall also be levied. [Penalty should be minimum and maximum as per bid security given in clause 8] In such situation, the bid will be considered further only if the amount of penalty is deposited before the completion of technical evaluation.

(h) The concern/firm/company whose product has been declared as of spurious or adulterated quality and any criminal case is filed and pending in any court shall not be eligible to participate for that particular product, in the Bid. Similarly convicted firm/company shall also not be eligible to participate in the Bid.

(i) If a company has two or more separate manufacturing units at different sites/states, the company will be allowed to submit only one Bid for all units but necessary document regarding separate manufacturing units will be submitted as a separate set with the same Bid. But a bidder will be allowed to submit only one offer for one product.

3. <u>PURCHASE PREFERENCE</u>

i. Purchase preference admissible to the PSUs of the state of Rajasthan and to the SSI of the state of Rajasthan, together shall not exceed 25% (10% for PSUs and 15% of SSI units ***or 25% preference may be given to PSU if there is no SSI unit to avail this benefit***). However these units will be required to participate in Bidding process and match L-1 price.

ii. **Comparison of rates of firms outside and those in Rajasthan:-**

While tabulating the Bids of those firms which are not entitled to price preference, the element of Rajasthan VAT shall be excluded from the rates quoted by the firms of Rajasthan and the element of CST shall be included in the rates quoted by the firms of outside Rajasthan. In such case if the price of any commodity being offered for sale by firms in Rajasthan is the same or lower (excluding Rajasthan VAT) than the price of firm outside Rajasthan (including element of CST), the commodity shall be purchased from the firm in Rajasthan.

iii. VAT on drugs and medicines are exempted in Rajasthan. RMSCL will issue necessary exempted certificate.

iv. RMSC will also issue "C-certificate" in case of interstate supply. Therefore concessional CST should be charged

4. GENERAL CONDITIONS

i. At any time prior to the date of submission of Bid, Bid Inviting Authority may, for any reason, whether on his own initiatives or in response to a clarification requested by a prospective Bidder, modify the condition in Bid documents by amendment. In order to provide reasonable time to take the amendment into account in preparing their bid, Bid Inviting Authority may at his discretion, extended the date and time for submission of Bids.

ii. Interested eligible Bidders may obtain further information in this regard from the office of the Bid Inviting Authority.

iii. In case any document submitted by the bidder or his authorized representative is found to be forged, false or fabricated, the bid will be rejected and Bid Security Deposit /Performance Security will be forfeited. Bidder/his representative may also be blacklisted/banned/debarred. Report with police station may also be filed against such bidder/his representative.

5. TECHNICAL BID

The Bidder should furnish the following in technical bid:-

(a) Bidders are allowed the option to quote for anyone item or more items as mentioned in bid (list of medicines proposed to be purchased at Annexure-VIII). The amount of Bid Security Deposit will remain @ Rs. 20,000/- per item of drug quoted subject to minimum of Rs.2.00 lacs and maximum of Rs.5.00 lacs.

(b) The bidders shall submit/upload scanned copy of all the challans, D.D./ BC/ e-deposit generated receipt in Technical Bid deposited for Bid document fees, RISL processing fee and Bid security. The required Bid Security Deposit / Bid document fees/ RISL fee may be in form of physical D.D./ BC along with letter. D.D. / bankers cheque shall be in favour of M.D. RMSCL (bid document fees and Bid Security Deposit), MD, RISL (bid processing fees).

(c) Those who wish to apply for Empanelment as supplier for Drugs and Medicines are required to deposit separately an Empanelment Fee of Rs

5000 (Five Thousand rupees only) in the form of DD /challan/e-deposit in favour of MD, RMSCL before due time and date of bid submission.

(d) Documentary evidence for the constitution of the company/Firm such as Memorandum and Articles of Association, Partnership Deed etc. with details of the Name, Address, Telephone Number, Fax Number, e-mail address of the firm and of the Managing Director/Partners/Proprietor.

(e) The Bidder should furnish attested copy of the valid License for the product duly approved by the Licensing authority for each and every product quoted as per specification in the Bid. The license must have been duly renewed/ valid up to date and the items quoted shall be clearly highlighted ***(Bid item codes marked against each item)*** in the license.

(f) Attested photocopy of the valid import license in Form 10 with Form 41 (as per Rule 122A of Drugs and Cosmetics Act), if the product is imported. The license must have been renewed /valid up to date. A copy of a valid license for the sale of Drugs imported by the firms issued by the licensing authority shall be enclosed.

(g) The instruments such as power of attorney, resolution of board etc., authorizing an officer of the Bidder should be enclosed.

(h) Authorization/nominating a responsible person of the Bidder to transact the business with the Bid Inviting Authority with photograph and signature in Annexure VII.

(i) Bidder should have at least 3 years market standing as a manufacturer for the items quoted in the bid.

For imported items, the quoted item should have 3 years market standing, for which bills of entry, sale invoices, etc should be submitted to establish the claim. The importing firm should have 3 years standing as importer / manufacturer of medicines in general. The manufacturer may submit his licence or MARKET STANDING CERTIFICATE to establish 3 years standing; The importer firm may submit Bills of entry, etc of same or other Surgical /Drugs to establish the market standing of the firm. The bidder shall submit valid import license for direct import of the quoted item.

(j) Market Standing Certificate issued by the Licensing Authority / competent authorities as a Manufacturer for the product for last 3 years (Certificate should be enclosed with list of items) should be enclosed. Items quoted should be highlighted in the market standing certificate. For imported items, the quoted item should have 3 years market standing, for which bills of entry, sale invoices, etc should be submitted to establish the claim. The importing firm should have 3 years standing as importer / manufacturer of medicines in general. The manufacturer may submit his licence or MARKET STANDING CERTIFICATE to establish 3 years standing; the importer firm may submit Bills of entry, etc of same or other drugs to establish 3 years for importing the items and to establish the market standing of the firm. **The MSC should not have been issued by competent authority more than 2 years old as on the last date of bid submission.** The bidder shall submit valid import licence for import of the quoted item. The market standing of products containing Paracetamol 500 mg shall be accepted in tablet combination where Paracetamol 325 mg is specified. However, for all above, the firm has to submit with bid, the product permission (from the Licensing Authority) as per bid specifications of the RMSC formula.

(k) Non-conviction Certificate issued by the Drugs Controller of the State. It should be recent and not more than one year old.

(l) WHO-GMP (WHO - Good manufacturing practices Certificate) Certificate issued by the Licensing Authority. The WHO-GMP certificate must not be older than one year from the due date of Bid submission in the case where validity is not mentioned in the certificate. ***The WHO-GMP certificate of all the manufacturing plants, of which products have been quoted, should be submitted.*** The Bidder shall also furnish an undertaking in the format given in Annexure-VII point no.8 declaring that the Bidder complies with the requirements of WHO-GMP. The Importer should produce WHO- GMP /COPP of the manufacturing firm or a certificate which is at par with WHO-GMP issued by exporting countries like US- FDA approval, etc. In the case of imported drugs,

labels and product literature of all quoted products must be submitted. **The Firm will continue to hold WHO-GMP Certificate for the product during entire rate contract period of the product. If WHO-GMP certificate expires, it is firm's responsibility to inform RMSCL about the same and not to accept any further purchase order till re-issue /renewal of WHO-GMP certificate. During the period of non validity of WHO-GMP certificate of the firm the rate contract will deemed to be suspended. If the firm fails to inform RMSCL about the expiry of WHO-GMP certificate and accept purchase order of RMSCL and later on it comes to the knowledge of RMSCL, such product of the firm shall be liable to be debarred for a period of two years from the date of order.**

(m) Annual turnover statement for 3 years i.e., 2012-13, 2013-14 and 2014-15 or 2013-14, 2014-15 and 2015-16 in the format given in Annexure-III certified by the practicing Chartered Accountant.

Explanatory Note:-

1) The merger / amalgamation / transfer of business / transfer of assets / share in sister concern / share in joint venture etc. of a firm affect the bid condition relating to 'Turnover' in preceding years. The eligibility of a bidder in this regard shall be ascertained by the Purchase Committee on the basis of the above stated agreement / BOD resolution / CA certificate or any other document(s) annexed with the tender documents and the decision of Purchase Committee shall be final.

2) **The amount shown as Turnover in the tender should be the amount as per VAT Act / other Acts and necessary documents / certificates shall be annexed with tender documents and accordingly eligibility of a bidder in this regard shall be ascertained by the Purchase Committee**.

(n) Copies of the Balance Sheet and Profit and Loss Account for three years i.e. 2012-13, 2013-14 and 2014-15 or 2013-14, 2014-15 and 2015-16 duly certified by the practicing Chartered Accountant.

(o) VAT/Sales Tax Clearance certificate (copies of latest challans), as on ***31.03.2016.***

(p) Registration with Excise Department, Govt. of India. The industries situated in excise free zones will be exempted from the registration provided they produce the copy of appropriate notification.

(q) Undertaking **(as in Annexure-VII)** for embossment of logo on labels of bottles, etc as the case may be, as per conditions specified at Clause 14 herein.

(r) Undertaking that the manufacturer has not been blacklisted, the product has not been declared as not of standard quality during last two years, it's manufacturing capacity and other details required on a format mentioned at Annexure-VII.

(s) Details of technical personnel employed in the manufacture and testing of drugs (Employee Name, Qualification, and Experience) as enclosed in license.

(t) List of items quoted to be shown in the **Annexure-VII** point number 6

(u) A **Checklist (Annexure-V)** for the list of documents enclosed with their page number. The documents should be serially arranged as per **Annexure-V**. Every bidder will also be required to submit details of product permission of the quoted item and the desired market standing, **in Annexure- VI**

(v) An undertaking that the bidder complies with all the terms, conditions, amendments (if any) of bid document to be submitted in **Annexure-VII point no.11.**

(w) A declaration under Section 7 of Rajasthan Transparency in Public Procurement Act, 2012 in Annexure-VII point no. 13

(x) ***All copies submitted should be self attested.***

(y) An undertaking in Annexure-XI that the bidder whishes to get empanelled as supplier for the quoted items and has submitted the necessary fee for the same. (This is only for those who apply for empanelment also). The bidders who have already paid empanelment fees in previous bid need not to submit the empanelment fee for the items being quoted in this bid. However the required annexure must be submitted.

(z) A copy of PAN issued by Income Tax Department.

Note:- 1. Clarification regarding submission of documents

It is found that some of the documents are sometimes not valid on the exact date of bid opening; the firm has submitted slightly older documents in the bid as it has not been able to get the new/renewed certificate issued from the concerned department till bid submission. Documents such as Non conviction certificate, WHO-GMP certificate & MSC shall be accepted if they have been issued after bid submission but submitted to Tendering authority when asked to do so in the form of clarification/short fall documents. But such documents shall be considered only if it is proved that the competence as certified by the competent authority regarding the required documents existed with the bidder on the date of submission of bid.

Note:- 2. Some additional relaxation for the following items

S. No	Code No.	Name of Item With Specification	Relaxation in condition
1.	398	Black Disinfectant Fluid (Phenyl) (As per Schedule "O" Grade – III	GMP (Good manufacturing practices Certificate) / WHO-GMP Certificate required.
2.	559	Betamethasone Lotion IP 0.05%	Product permission, Market Standing Certificate and Performance Statement of two year acceptable.

6. PRICE BID –

The price bid will also be known as financial document and every bidder will be required to submit its price in excel format attached to the bid document (BOQ). **BOQ template must not be modified/ replaced by the bidder and the same should be uploaded after filling the relevant columns, else the bidder is liable to be rejected for this bid. Bidders are allowed to enter the bidder name and values only**. **The bidder should quote rate for the mentioned packing unit only.**

7. **OPENING OF TECHNICAL AND FINANCIAL EVALUATION**

The Bid will be scrutinized by Bid evaluation committee and inspection of manufacturing unit for compliance of WHO-GMP may be carried out by

technical committee. Price Bid (BOQ) of the Bidder found eligible on satisfying the criteria for technical evaluation and inspection, will only be opened.

8. **BID SECURITY**

The Bid Security shall be @ Rs. 20,000/- for each item of Drugs & Medicines quoted subject to minimum of Rs. 2.00 lacs and maximum of Rs. 5.00 Lacs. In case Bid Security submitted by the bidder is at the minimum or more but number of quoted items is more than the Bid Security submitted, the quoted items by the bidder will be counted in sequence up to the Bid Security deposited. However without minimum Bid Security the offer will not be considered at all., Bid Security will not be taken from undertakings, corporation of GoI & GoR. Further, Bid Security will be taken @ Rs. 5,000/- per item of Drugs & Medicines quoted subject to minimum of Rs. 50,000/- and maximum of Rs. 1.25 Lacs, from SSI Units of Rajasthan. They will furnish copy duly attested by gazetted officer of the registration of SSI units issued by the Director of Industries in respect of the stores for which they are registered. Duly attested copy of Acknowledgement of EM-II issued by DIC with an affidavit worth Rs.10 as per Annexure-II under preference to Industries of Rajasthan rules 1995 in respect of stores for which they are registered. **(Annexure-II**). In case Bid Security submitted by the bidder is at the minimum or more but number of quoted items is more than the Bid Security submitted, the quoted items by the bidder will be counted in sequence up to the number matching the Bid Security deposited. However without minimum Bid Security the offer will not be considered at all.

The Bid Security shall be paid in through separate prescribed challans (format enclosed in Annexure-I) in any branch of the Punjab National Bank Account no. 2246002100024414 throughout country upto 29.08.2016 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSC by 1.30 PM on 30.08.2016 Bid security Deposit in any other form will not be accepted. ***Alternatively bidder may also deposit Bid document fees, Bid security and RISL processing fees by way of e-deposit, through Internet Banking by accessing RMSC website rmsc.nic.in clicking e-deposit icon following the laid down steps; Rs.25 plus applicable service tax will be the per***

transaction charge to be debited in respective depositor's account after successful e-deposit. Supplier should enclose the generated receipt.

The Bids submitted without sufficient Bid Security will be summarily rejected. The Bid Security will be forfeited, if the Bidder withdraws its Bid after last time & date fixed for receiving bids or in the case of a successful Bidder, if the Bidder fails within specified time to sign the contract agreement or fails to furnish the performance security.

9. **OTHER CONDITIONS**

1. The orders will be placed by the Managing Director or any officer designated, Rajasthan Medical Services Corporation Ltd, (hereinafter referred to as Ordering Authority).
2. The details of the required drugs, medicines, etc., are shown in **Annexure-VIII.** The quantity mentioned is only the tentative requirement and may increase or decrease as per the decision of Ordering Authority. The rates quoted should not vary with the quantum of the order or the destination. ***The commitment quantity for an item submitted by the bidder (in Annexure VII) shall be taken in to account and a bidder not having adequate capacity (as reflected in commitment quantity) may be technically disqualified.***
3. Bid has been called for in the **generic names of drugs**. The Bidders should quote the rates for the generic products. The composition and strength of each product should be as per details given in **Annexure-VIII.** Any variation, if found, will result in rejection of the Bid. The products should conform to the specified standards IP/BP/USP. In case the product is not included in the said compendium, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing.
4. Rates (inclusive of Excise Duty, Customs duty, transportation, insurance, and any incidental charges, but exclusive of Sales tax) should be quoted for each of the required drugs, medicines etc., separately on door delivery basis according to the unit ordered. Bid for the supply of drugs, medicines, etc. with conditions like "AT CURRENT MARKET RATES" shall not be accepted. Handling, clearing, transport charges etc., will not be paid. The delivery should be made as stipulated

in the purchase order placed with successful Bidders. No quantity or cash discount should be offered.

5.

a) To ensure sustained supply without any interruption, the Bid Inviting Authority reserves the right to fix more than one supplier to supply the requirement among the qualified Bidders

b) Orders will be placed periodically during rate contract period based on the stock positions only. Orders will be placed with L1 firms.

The orders may split between L-1 and rate matched firms. Quantities may be divided between L1 and matched L1 as 80:20. In case L2 and L3 match L1 than quantities may be divided as 75:15:10. Whenever L2 or L3 firms are more than one, then quantity would be distributed equally.

c) After the conclusion of Price Bid opening, the lowest offer of the Bidder, if required will be considered for negotiations, and rate arrived after negotiations will be L-1 rate and L-1 supplier for an item of drugs/medicines for which the Bid has been invited.

d) The Bidder who has been declared as L-1 supplier for certain item or items of drugs/medicines shall execute necessary agreement for the supply of the Bided quantity of such drugs/medicines as specified in the Bid document on depositing the required amount as performance security and on execution of the agreement, such Bidder is eligible for the placement of purchaser orders. ***Moreover, purchase order can be placed after the issue of letter of acceptance, pending the execution of agreement and issuance of rate contract for an item.***

e) RMSC will inform the L1 rate to the Bidders who qualified for Price Bid opening, through RMSC web site or e-mail; willing bidders may inform in writing their consent to match with the L-1 rate for the item of the Drugs/Medicines quoted by them and the Bidders who agree to match L1 rate, will be considered as Matched L1.

f) The Bidder, who agrees to match L-1 rate shall furnish the breakup detail (Rate, CST, VAT etc.) of price (L-1 rate).

g) The supplier upon receipt of the purchase order deems that the purchase orders exceeds the production capacity declared in the Bid documents and the delay would occur in executing the order, shall inform the RMSC immediately without loss of time and the purchase orders shall be returned within 7 days from the date of the order, failing which the supplier is stopped from disputing the imposition of liquidated damages, fine for the delayed supply.

h) If the L1 supplier has failed to supply /intimated RMSC about his inability/delay in supply as per the purchase order, the required Drugs/ Medicines within the stipulated time or as the case may be, RMSC may also place purchase orders with the Matched L1 Bidder for purchase of the Drugs/Medicines, provided such matched L1 Bidders shall execute necessary agreement indicating the production capacity as specified in the Bid document on depositing the required amount. Such Bidder is eligible for the placement of purchase orders for the item or items of Drugs/Medicines quoted by them.

i) Subject to Para (h) above, while RMSC has chosen to place purchase orders with Matched L1 supplier and there are more than one such matched L1 suppliers, then the purchase orders for the requirement of Drugs/Medicines will be placed with L-2 first on matched rates of L-1 and in case L-2 does not have the required capacity than L-3 would be considered on matched L-1 rates and the same order would be followed in case of L-3, L-4 etc.

j) The matched L1 supplier, on placement of purchase orders, will be deemed as L-1 rate supplier for the purpose of the Bid and all provisions of the Bid document applicable to L-1 rate Bidder will apply mutatis mutandis to the matched L1 supplier.

k) If the purchase order quantity is very less (which do not make even a normal small batch size; order quantity is less than 1 lac Tab/Cap, or less than 10,000 injections/ bottles/ tubes), the supply may be allowed in brand name to ensure uninterrupted sustained supply. However, the label should possess the required logogram, and the price should not appear on the label.

6. The rates quoted and accepted will be binding on the Bidder during validity period of the bid and any increase in the price (except increase due to Excise Duty or any other statutory taxes) will not be entertained.
7. No Bidder shall be allowed at any time on any ground, whatsoever it may be, to claim revision or modification in the rates quoted by him after last date fixed for receipt of bid. Representation to make correction in the Bid documents on the ground of Clerical error, typographical error, etc., committed by the Bidders in the Bids shall not be entertained after submission of the Bids. Conditions such as "SUBJECT TO AVAILABILITY" "SUPPLIES WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED" etc., will not be entertained under any circumstances and the Bids of those who have given such conditions shall be treated as incomplete and accordingly the Bid will be rejected.
8. The rates should be quoted only for the composition stated in the Bid.
9. Supplies should be made directly by the bidder and not through any other agency.
10. The Bidder shall allow inspection of the factory at any time by a team of Experts/Officials of the Bid Inviting Authority and or of the Govt. of Rajasthan. The Bidder shall extend all facilities to the team to enable to inspect the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If a Company/Firm does not allow for any such inspection, its Bids will be rejected. ***The firms/companies selected to supply the quoted product /products shall be inspected within 3 months after entering into contract with the firm.***

10. ACCEPTANCE OF BID

1. The Bid evaluation committee formed by Managing Director, Rajasthan Medical Services Corporation Ltd. will evaluate the Bid with reference to various criteria.
2. Bid Inviting Authority reserves the right to accept or reject the Bid for the supply of all or any one or more items of the drugs Bided for in a Bid without assigning any reason.
3. Bid Inviting Authority, or his authorized representative (s) has the right to inspect the factories of Bidders, before, accepting the rate quoted by them, or before releasing any purchase order(s), or at any point of time during the continuance of

Bid and also has the right to reject the Bid or terminate/cancel the purchase orders issued and or not to reorder, based on adverse reports brought out during such inspections.

4. The acceptance of the Bids will be communicated to the successful Bidders in writing by the Bid inviting authority. Immediately after receipt of acceptance letter, the successful Bidder will be required to deposit PERFORMANCE SECURITY and agreement but not later than 15 days.
5. The approved rates of the successful Bidders would be valid as Rate contract and ending on **30.09.2018** ***(w.e.f date of letter of acceptance)*** and may extendable by 3 months.
6. ***Moreover, purchase order can be placed after the issue of letter of acceptance, pending the execution of agreement and issuance of rate contract for an item.***

11. **PERFORMANCE SECURITY**

The Successful Bidders shall be required to pay performance Security Deposit @ 5% of the Contract value. Performance security will not be taken from undertaking, corporation of GoI & GoR.. The SSI Units of Rajasthan shall be required to pay Performance security @ 1% of the contract value.

The performance security shall have an upper limit of Rs 25 Lac to be deposited by a bidder at the time of signing of agreement (For one or many items). However, when the actual purchase orders cross a threshold for requiring additional security (remaining rate contract period with additional one year), the same will be required to be deposited by the supplier.

The performance guarantee should be paid upfront in respect of each contract on or before the due date fixed by Bid inviting authority in the form of Bank Guarantee **(Performa given in Annexure XIV)** in case the amount exceeds Rs 5 Lakhs. For amount of upto 5 Lakhs it should be deposited in the form of demand draft/bankers cheque issued by a scheduled bank or may be deposited through challan annexure 1 (the validity of bank guarantee should be for a period of ***thirty six month*** from the date of issuance of Bank Guarantee) in favor of the Managing Director, Rajasthan Medical Services Corporation Ltd, Payable at Jaipur, viz. Bid inviting authority before releasing the purchase order by the ordering authority. In case L-2 and L-3 bidders who have agreed to match L-1

price, then the ***performance security*** Deposit of L-2 and L-3 bidders will be ***5% of value of their assured quantity (upper limit Rs 25 Lac) and in case L-4, L-5 and so on bidders who have agreed to match L-1 price bidders will be converted (Rs 20000/- per item) into security deposit.*** In case of inability of L-1 bidder to supply the required quantity of drugs, in that case the L-2 and L-3 supplier (as the case may be) will be asked to supply the drugs. At the time of placing of order these matched suppliers will be asked to deposit amount of balance security for a period of ***remaining rate contract period with additional one year.***

Performance Security shall remain valid and refunded 60 days beyond the date of completion of all contractual obligations or after 36 months from the date of issuance of letter of acceptance, whichever is later.

12. AGREEMENT

a) The successful Bidder shall execute an agreement on a non-judicial stamp paper of value mentioned in the Acceptance Letter (stamp duty to be paid by the Bidder) within 15 days from the date of the intimation **letter of intent** by the Bid Inviting Authority, viz., the **Managing Director, Rajasthan Medical Services Corporation Ltd**. The Specimen form of agreement is available in **Annexure-IV, failing to submission of performance security and execution of agreement within 15 days as stipulated, will result in forfeiture of Bid Security Deposit & other consequential action.**

b) The Bidder shall not, at any time, assign, sub-let or make over the contract or the benefit therefore or any part thereof to any person or persons whatsoever.

c) All notices or communication relating to, or arising out of this agreement or any of the terms thereof shall be considered duly served on or given to the Bidder if delivered to him or left at the premises, places of business or abode.

13. SUPPLY CONDITIONS

1. Purchase orders along with the delivery destinations will be placed on the successful Bidder at the discretion of the Ordering Authority. Drugs and Medicines will be supplied at 34 district drug ware houses and 6 Medical College Warehouses of Rajasthan.

2. The supplier shall supply the entire ordered quantity before the end of **45 days** from the date of issue of purchase order at the destinations mentioned in the purchase order, if the above day happened to be a holiday for RMSC, the supply should be completed by 5.00 p.m. on the next working day. For drug items requiring sterility test and imported ones, the supply period will be **60 days** from the date of issue of purchase order.
3. All supplies will be scheduled for the period from the date of purchase order till the completion of the bid in installments, as may be stipulated in the purchase order.
4. **Shelf Life**: The labeled shelf life of drugs supplied should be not less than the period mentioned against each item in list of Drugs (Annexure-VIII). The remaining shelf life of the drugs at the time of delivery should not be less than ¾ of the labeled shelf life. **Only those bidders shall quote who can manufacture and supply the product with the required shelf life. The product of labeled shelf life lesser than required shelf life will not be accepted. The product should not have such storage condition requiring it to be stored below 2°C.**

   Quality Assurance: The supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of specifications and related documents (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purpose made; (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per WHO-GMP.

   In case of imported items the remaining shelf life of 60% or more may be accepted with an undertaking that the firm will replace the unused expired stores with fresh goods. However, firms supplying drugs with remaining shelf life of 75% or more need not submit such undertaking.
5. The protocol of the tests should include the requirements given in I.P for tablets and those required specifically for the product specifications. The Bidder must submit its Test/ Analysis Report for every batch of drug along with invoice. In case of failure on the part of the supplier to furnish such report, the batch of drugs will be returned back to the supplier and he is bound to replenish the same with approved laboratory test report. The supplier shall provide the validation data of the analytical procedure used for assaying the components and shall

provide the protocols of the tests applied and the placebo material when demanded for the purpose of testing.

6. The Drugs and medicines supplied by the successful Bidder shall be of the best quality and shall comply with the specification, stipulations and conditions specified in the Bid documents.
7. If supplies are not fully completed in **45 days** from the date of the Purchase Order (**60 days** for drugs of the category of serum, vaccine, enzymes, blood grouping reagents, biological products, powder for injections and imported drugs), the provisions of liquidated damages of Bid conditions will come into force. The Supplier should supply the drugs at the Warehouse specified in the Purchase Order and if the drugs supplied at a designated places other than those specified in the Purchase Order, transports charges will be recovered from the supplier.
8. If the supplier fails to execute at least 50% of the quantity mentioned in single purchase order and such part supply continues for three consecutive Purchase orders, then the supplier will be ineligible to participate in any of the Bids for particular items of drugs/medicines for a period of two year immediately succeeding year in which supplier has been placed Purchase order.
9. If the Bidder fails to execute the supply within the stipulated time, the ordering authority is at liberty to make alternative purchase of the items of drugs and medicines for which the Purchase orders have been placed from any other sources **(such as Public Sector undertakings at their rates, empanelled bidders, and bidders who have been technically qualified in the said bid)** or in the open market or from any other Bidder who might have quoted higher rates at the risk and the cost of the supplier and in such cases the Ordering Authority/Bid inviting authority has every right to recover the cost and impose penalty as mentioned in Clause 19, apart from terminating the contract for the default.
10. The order stands cancelled after the expiration of delivery period, and if the extension is not granted with or without liquidated damages. Apart from risk/alternate purchase action, the Bidder shall also suffer forfeiture of the

performance security and shall invite other penal action like blacklisting/Debarring disqualification from participating in present and future Bids of Bid Inviting Authority/ordering authority. . (As per guidelines for blacklisting/ debarring at annexure- IX including amendment)

11. It shall be the responsibility of the supplier for any shortage/damage at the time of receipt at the designated places.
12. If at any time the Bidder has, in the opinion of the ordering authority, delayed in making any supply by reasons of any riots, mutinies, wars, fire. storm, tempest or other exceptional cause on a specific request made by the Bidder within 7 days from the date of such incident, the time for making supply may be extended by the ordering authority at its discretion for such period as may be considered reasonable. The exceptional causes do not include the scarcity of raw material, Power cut, labour disputes.
13. The supplier shall not be in any way interested in or concerned directly or indirectly with, any of the officers, subordinates or servants of the Bid Inviting Authority in any trade or business or transactions nor shall the supplier give or pay promise to give or pay any such officers, subordinates or servants directly or indirectly any money or fee or other considerations under designation of "Customs" or otherwise, nor shall the supplier permit any person or persons whom so ever to interfere in the management or performance hereof under the power of attorney or otherwise without the prior consent in writing of the Bidder Inviting Authority.
14. ***If the supplier, or any of its approved items gets debarred/banned/blacklisted in any states after entering into agreement with RMSC, it shall be the responsibility of the supplier to inform RMSC without any delay about the same.***
15. ***If a supplier fails to execute two successive orders, in full, firm will be liable for debarment the particular product, for a year.***
16. ***If a supplier fails to execute first order, without proper justification, a show cause notice may be given to him to respond within 7 days. If it does not respond or does not give reasonable justification, the corporation may order to L-2 and L-3, for entire failed supply on L-1 matched rate. If L-2 and L-3***

matched rates are not available, then only purchase may be made on 'Risk and cost basis' as being done presently. Subject to other condition of Bid documents.

17. The supplier of sevoflurane anesthetic **(Item code no. 491)** shall install vaporizers on loan basis free of cost, in required numbers, as per the need of the Healthcare facilities/ institutions. **The installation report of the vaporizers should be submitted along with the invoice.**

14. LOGOGRAMS / Markings

Logogram means, wherever the context occurs, the design as specified below:-

DESIGNS FOR LOGORAMS

Logogram for item code except 448W, 489P and 490W	Logogram for item code 448W, 489P and 490W
RAJASTHAN MEDICAL SERVICES CORPORATION RMSC	NATIONAL HEALTH MISSION राष्ट्रीय स्वास्थ्य मिशन

INJECTIONS

Injection in ampoule form should be supplied either in Double constricted neck ampoules or snap off type ampoules with the label bearing the words "Rajasthan Govt. Supply- Not for sale निःशुल्क वितरण हेतु, QC – Passed" overprinted and the following logogram which will distinguish from the normal trade packing. Name of drug should be printed in English and Hindi languages and should be legible and be printed more prominently. Storage directions should be clear, legible, preferably with yellow highlighted background.

RAJASTHAN MEDICAL SERVICES CORPORATION RMSC

The vials should be supplied with aluminum seals containing the following logogram:

LIQUIDS

Liquid preparations should be in bottles with pilfer-proof caps bearing the following logogram:

Logogram for item code except 448W, 489P and 490W	Logogram for item code 448W, 489P and 490W

The top of the cap and the label to be affixed on the containers should bear a distint colour different from the colour of the label of the trade packs and they should be overprinted in red colour with the words **"Rajasthan Govt. Supply- Not for Sale निःशुल्क वितरण हेतु, QC – Passed"** and the logogram. Name of drug should be printed in English and Hindi languages and should be legible and be printed more prominently. Storage directions should be clear, legible, preferably with yellow highlighted background.

OINTMENTS & CREAMS

Ointments & Creams should be supplied in tubes bearing the following logograms and the words **"Rajasthan Govt. supply- Not for sale निःशुल्क वितरण हेतु, QC – Passed"**

overprinted. Name of drug should be printed in English and Hindi languages and should be legible and be printed more prominently. Storage directions should be clear, legible, preferably with yellow highlighted background.

TABLETS & CAPSULES

Tablets and Capsules should be supplied in Strips or Blisters or as mentioned in the list of items for bid. The strip, etc, should bear the following logograms and the words **"Rajasthan Govt. supply- Not for sale** निःशुल्क वितरण हेतु, **QC – Passed"** overprinted. Name of drug should be printed in English and Hindi languages and should be legible and be printed more prominently. Storage directions should be clear, legible, preferably with yellow highlighted background.

Logogram for item code except 448W, 489P and 490W	**Logogram for item code 448W, 489P and 490W**

SPECIMEN LABEL FOR OUTER CARTON

SHALL BE OF DIFFERENT COLOURS FOR DIFFERENT CLASS OF DRUGS

-

RAJASTHAN GOVT. SUPPLY
NOT FOR SALE

(Name of Drugs etc.)

CONSTITUENTS OF……..
Name of the Drug, Manufactured by, Batch no
Mfg.Date, Exp. Date, Quantity/Kit

Net. Weight:……..Kg

Manufactured by/Assembled by

The name of the drug shall be mentioned in Hindi and English and should be legible and be printed more prominently. **A uniform colour theme and artwork will be necessary.** Apart from this "F**or Govt. of Rajasthan – Not for Sale** निःशुल्क वितरण हेतु, **QC – Passed"** along with logo of RMSCL will be printed on each strip/label of the bottle. The storage directions should be clear, legible and preferably with yellow highlighted background.

1. Bids for the supply for Drugs and medicines etc., shall be considered only if the Bidder gives undertaking in his Bid that the supply will be prepared and packed with the logogram printed on the strips of tablets and capsules and labels of bottles, ampoules and vials etc., as per the design mentioned above.
2. All tablets and capsules have to be supplied in standard packing in aluminum strip or blisters with aluminium foil back with printed logogram and shall also conform to schedule P1 of the Drugs & Cosmetics Act & Rules wherever it applies. Affixing of stickers and rubber stamps shall not be accepted.
3. Labels of Vials, Ampoules and Bottles containing the items Bided for should also carry the logogram.
4. Failure to supply Drugs etc., with the logogram will be treated as breach of the terms of agreement and liquidated damages will be deducted from bills payable as per conditions in Clause 18.2 Bidders who are not willing to agree to conditions above will be summarily rejected.
5. In case of imported drugs affixing rubber stamp on the original label is allowed with indelible ink on inner most and outer packing.

15. PACKING

1. The item shall be supplied in the package schedule given below and the package shall carry the logogram specified in clause -14. The labeling of different packages should be as specified below. The packing in each carton shall be strictly as per the specification mentioned. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties.
2. The pediatric drops should always be supplied with dropper. A measuring cap with suitable markings must be provided for other paediatric oral liquid preparations.
3. The labels in the case of injectables should clearly indicate whether the preparations are meant for IV, IM, SC, etc.
4. Injection vials should have flip off seals.
5. All plastic containers should be made of virgin grade plastic.
6. The name of the drug should be printed in clearly legible bold letters (It is advisable that the colour of font be different from other printed matter to make the name highly conspicuous.
7. It should be ensured that only first hand fresh packaging material of uniform size is used for packing. All packaging must be properly sealed and temper proof.
8. All packing containers should strictly conform to the specifications prescribed in the relevant pharmacopoeia/Act.
9. Packing should be able to prevent damages or deterioration during transit.
10. In the event of items supplied found to be not as per specifications in respect of their packing, the Ordering Authority is at liberty to make alternative purchase of the item for which the purchase orders have been placed from any other sources or from the open market or from any other Bidder who might have quoted higher rates at the risk and the cost of the supplier. In such cases the ordering authority has every right to recover the cost and impose penalty as mentioned in Clause 18.2 and 19.

I. SCHEDULE FOR PACKAGING OF DRUGS AND MEDICINES GENERAL SPECIFICATIONS

No corrugate package should weigh over 15 kgs (i.e. product + inner carton + corrugated box).

All items should be packed only in first hand strong boxes only.

Every corrugated box should preferably be of single joint and not more than two joints.

Every box should be stitched using pairs of metal pins with an interval of two inches between each pair.

The flaps should uniform meet but should not overlap each other. The flap when turned by 45-60 should not crack.

Every box should be sealed with gum tape running along the top and lower opening.

CARRY STRAP:

Every box should be strapped with two parallel nylon carry straps (they should intersect.)

LABEL:

Every corrugated box should carry a large outer label clearly indicating that the product is for "Rajasthan Govt. Supply-Not for Sale".

The Product label on the cartoon should be large, atleast 15 cms x 10 cms dimension. It should carry the correct technical name, strength or the product, date of manufacturing, date of expiry quantity packed and net weight of the box.

OTHERS:

NO box should contain mixed products or mixed batches of the same product.

II. SPECIFICATION FOR CORRUGATED BOXES HOLDING TABLETS/CAPSULES/PESSARIES

1. The total weight of the box should be approx of 7-8 Kgs.

III. SPECIFIATION FOR LARGE VOLUME BOTTLE i.e., ABOVE 100 ml AND BELOW 1 LIT.

1. All these bottles should be packed only in single row with partition between each and also with top and bottom pad of 3 ply.

IV. SPECIFICATION FOR IV FLUIDS

Each corrugated box may carry maximum of only 24 bottles of 500 ml in a single row or 50 bottles of 100 ml in 2 rows with individual sealed polythene cover and centre partition pad, top and bottom pads of 3 ply.

V. SPECIFICATION FOR LIQUID ORALS

100 bottles of 50 ml or 60 ml may be packed in a single corrugated in 2 rows with top, bottom and centre pad of 3 ply.

50 bottles of 100 ml – 120 ml may be packed in a similar manner in a single corrugated box.

If the bottles are not packed in individual carton, 3 ply partition should be provided between each bottle. The measuring device should be packed individually.

VI. SPECIFICATION FOR OINTMENT/CREAM/GELS PACKED IN TUBES:

No corrugated box should weigh more than 7-8 Kgs.

Every Ointment/Cream/Gel tube should be individually packed in carton and then packed in 20's in a grey board box, which may be packed in a corrugated box.

VII. SPECIFICATIONS FOR INJECTION (IN VIALS AND AMPOULES)

Vials may be packed in corrugated boxes weighing upto 15 Kgs. Ampoules should be packed in C.B weighing not more than 8 Kgs.

In the case of 10 ml Ampoules or 50 ampoules may be packed in a grey board box. Multiples of grey board boxes packed in CB. In case of ampoules larger than 10 ml only 25 ampoules may be packed in a grey board box with partition.

If the vial is packed in individual cartoon, there is no necessity for grey board box packing. The individual cartoon may be packed as such in the CB with centre pad.

In case of ampoules every grey board box should carry 5 amps alongwith Cutters placed in a polythene bag.

Vials of eye and ear drops should be packed in a individual cartoon with a dispensing device. If the vial is of FFS/BFS technology, they should be packed in 50's in a grey board box.

Cutters are not required with ampoules in the case of snap off type ampoules.

VIII. SPECIFICATION FOR ORS

Primary Packing:- The pouches/sachets of ORS should be three layered with following composition

Site	Material	Micron	MM	g/m^2
Inner	Polyethylene	50	0.040-0.050	36.9-46.1
Middle	Aluminium	09	0.009-0.015	24.3-40.5
Outside	Polyester	12	0.012-0.015	12.9-20.9

Secondary Packages and Tertiary package:-

50 sachets may be packed in grey board boxes and 10 grey board boxes in a C.B.

IX. LYSOL

Not more than four 5 liters cans may be packed in a single Box.

Government of India Guidelines

15(A) ITEM CODE 490W - IRON AND FOLIC ACID TABLETS (WIFS JUNIOR)

A. SPECIFIC REQUIREMENTS

Item:

Iron and Folic acid tablets (By brand name of WIFS JUNIOR) shall conform to the requirements given in IP 2014 given under Iron & Folic Acid (IFA) Tablets and the general requirements of Tablets given in IP 2014. In addition it should comply with the requirements given in the Annexure-WIFS JUNIOR.

The drug shall be currently registered in India and shall meet all requirements of the licensing authorities of India.

Description:

Iron and Folic Acid Tablets (WIFS-JUNIOR) contain Ferrous Sulphate and Folic Acid. They are "Sugar Coated" and "Pink" colored tablets. Only Edible colors should be used.

Each sugar coated WIFS Junior IFA tablet shall contain:

	Small
Dried Ferrous Sulphate IP equivalent to ferrous iron	45 mg
Folic Acid IP	0.4 mg

The quality of each constituent should conform to the requirements of IP.

Protocol and Testing:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.

Protocols of tests should include the requirements given in IP 2014 under Iron & Folic Acid Tablets and the general requirements for Tablets including those specified in the Annexure.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.

Each batch should be accompanied with a certificate from the manufacture that the drugs meet the specified requirements.

Random batches will be taken from the supplies of the State (post-delivery) and will be periodically tested (quarterly/six monthly) by DoHFW / MoHFW in identified labs separately for monitoring quality assurance.

Storage:

Iron and Folic Acid Tablets (IFA) should be protected from light/moisture/rodents/damage to packaging.

Shelf-life:

24 months, at least 5/6th of the shelf life of IFA must remain at the time of receiving the shipment. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package.

Labelling:

The label on each strip of WIFS-JUNIOR shall conform to the requirements of Rule 96 of Drugs & Cosmetic Rules and shall appear in English.

All labeling of WIFS-JUNIOR should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Rule 96 of Drug & Cosmetic Rules, all labels shall state the amount of ferrous sulphate and equivalent amount of Ferrous iron & Folic Acid, the name of the manufacturer, manufacturing license number, address of manufacturer, batch number, and expiry date.

Labeling for secondary packaging:

A label of WIFS-JUNIOR must be affixed either on the top and/or front surface of the secondary package. It should indicate the number of strips/tablets, the amount of ferrous sulphate and equivalent amount of Ferrous iron & Folic Acid, the name of WIFS-JUNIOR drug manufacturer, batch number, date of manufacture, date of expiry, and storage conditions.

Labeling for tertiary packaging (insulated packaging):

The external surface of insulated packages should be either white or in the natural color of corrugated carton. The label should in both English and Hindi/local language of the State.

The labels of WIFS-JUNIOR on tertiary packaging must be attached to at least two sides. The label should include the name of the product "IFA WIFS-JUNIOR" the number of secondary packages (boxes)/strips/tablets, the name of the manufacturer, batch number, date of manufacture, and date of expiry.

Numbering of tertiary packaging:

All boxes should be numbered consecutively. Shipping documents should be included in the box labeled number l.

Additional Labeling:

All the containers and other outer containers shall be marked with the statement "GOVT SUPPLY-NOT FOR SALE" in English and Local language.

All labels on containers i.e. strips, cartoons etc. should be marked with the statement "GOVT SUPPLY-NOT FOR SALE" in bold letters in English and local language.

B. QUALITY ASSURANCE

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per cGMP included in Schedule M of Drugs & Cosmetic Rules.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The Supplier shall provide the validation data of the analytical procedure used for assaying the components.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to / after the shipment of the product.

Testing:

The Purchaser may cause independent laboratory testing of the samples picked randomly from pre and post-delivery shipment to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on the product.

C. PACKING :

Primary Package:

15 Tablets should be packed in an Aluminium -Aluminium strip with IFA-WIFS JUNIOR name displayed prominently.

Aluminium Strips: Thickness of Aluminium Foil: 40 microns with LDPE 25 micron coating /heat seal lacquer.

- Toll free number must be indicated on every secondary package for contacting in case of product complaints.

Secondary Package:

The strips should be packaged in boxes for easy handling, transport and distribution with WIFS name displayed prominently. The box may contain 10 strips. It shall be fabricated from Millboard/ grey board/ card board with a minimum of bursting strength of 400 gsm.

- Toll free number must be indicated for contacting in case of product complaints.

Tertiary Package:

The boxes shall be packed in weather resistant triple walled insulated corrugated 5-ply cartons, each ply having strength of minimum 150 gsm with WIFS name displayed prominently. It should be fabricated from virgin quality "A" grade material. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.

- Toll free number must be indicated for contacting in case of product complaints.

D. QUALIFICATION OF THE MANUFACTURER:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to cGMP Standards and Schedule M of Drugs & Cosmetic Rules.

E. RECALLS:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged 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 quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

In case the quality of the product is found to be sub-standard or unsatisfactory in quality checks, stringent action would be taken against them and the supplier can be black-listed for future supplies of the product.

F. COLOUR CODING:

The Labels on secondary packing, tertiary packing and shipper package shall be identified by background. (Standard Pink Color).

G. BAR CODING:

Bar code shall be used to track down the product. It shall be printed on the label of Millboard/Grey board boxes and 5-Ply shipper containing

1. Product identification (GTIN 14) using application identifier (01)
2. Expiry date in YYMMDD format & using application identifier (17)
3. Master batch number using application identifier (10)
4. Bar coding to be put on all Tertiary and Secondary Packing.

Complete details on GSI standards along with technical guidelines can be downloaded from www.gs1india.org or www.gs1.org

i. MARKINGS:

All containers and invoices must bear the IFA-WIFS JUNIOR name of the product, expiry dates of and appropriate storage conditions.

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Name IFA-WIFS JUNIOR
- Generic name of the product
- Manufacturer's name and registered address
- Manufacturer's License number
- Lot or batch number
- Number of strips contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling
- Place of manufacture
- Barcode

Exterior Shipping Cartons :

The following information shall be stenciled or labeled on the exterior shipping cartons on all four sides in bold letters at least **Ariel font size 14** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Name IFA – WIFS JUNIOR
- Generic name of the product
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)

- Manufacturer's name and registered address

Consignee's address and emergency phone number including mobile number

- Contract number
- Number of tablets/strips/boxes contained in the carton
- Gross weight of each carton (in kg)
- Carton containing no. of …. Secondary packages
- Instructions for storage and handling
- Place of manufacture
- Barcode

ii. <u>Documentation:</u>

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be supplied must be sent at least seven days in advance of arrival of the consignment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) shall be intimated well in advance by registered letter/e-mail/telephone, so that the products are collected immediately after arrival.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB) if applicable;
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) as per the requirements issued by the Regulatory authority for each lot and
- Any other document, certificate or instruction specified in the individual order.

The documents shall be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages and gross weight(in Kilograms);
- Value of shipment(in Indian Rupees);
- A WB and Flight number(s) if applicable;
- Date and time for place of departure, transit (if applicable), and arrival;

-

- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.
- Invoice

The following information shall be stated on the invoice:

- Consignee's name, address, telephone number (including mobile no.) and e-mail ID.
- Purchase order reference;
- Consignee's requisition reference;
- Instructions to:"Telephone consignee upon arrival (repeat telephone number);

iii. <u>DISPATCH</u>

Consignments should be scheduled to arrive outside weekends and/or public holidays.

Annexure WIFS JUNIOR

Additional tests: Ferrous Sulphate and Folic Acid Tablets

The method of analysis should be validated as per ICH guidelines

Seals Integrity Test:

Check 10strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Re-establish normal pressure and open strips to examine for water penetration

Microbial Count:

When the test is conducted as per IP

-Total viable aerobic count-Not more than 10^3 bacteria and not more than 10^2 fungi per gram

-Absence of Escherichia coli

15(B). ITEM CODE 489P- IRON AND FOLIC ACID TABLETS (IFA-WIFS)

A. SPECIFIC REQUIREMENTS

Item:

Iron and Folic acid tablets (By brand name of IFA WIFS) shall conform to the requirements given in IP 2014 given under Iron & Folic Acid (IFA) Tablets and the general requirements of Tablets given in IP 2014. In addition it should comply with the requirements given in the Annexure IFA-WIFS.

The drug shall be currently registered in India and shall meet all requirements of the licensing authorities of India.

Description:

Iron and Folic Acid Tablets **(IFA-WIFS**) contain Ferrous Sulphate and Folic Acid. They are "enteric Coated" and "Blue" colored tablets (Indigo Carmine). Only Edible colors should be used.

Each enteric coated IFAWIFS tablet shall contain:

	Small
Dried Ferrous Sulphate IP equivalent to ferrous iron	100 mg
Folic Acid IP	0.5 mg

The quality of each constituent should conform to the requirements of IP.

Protocol and Testing:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.

Protocols of tests should include the requirements given in IP 2014 under Iron & Folic Acid Tablets and the general requirements for Tablets including those specified in the Annexure.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.

Each batch should be accompanied with a certificate from the manufacture that the drugs meet the specified requirements.

Random batches will be taken from the supplies of the State (post-delivery) and will be periodically tested (quarterly/six monthly) by DoHFW / MoHFW in identified labs separately for monitoring quality assurance.

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Storage:

Iron and Folic Acid Tablets (IFA) should be protected from light/moisture/rodents/damage to packaging.

Shelf-life:

24 months, at least 5/6th of the shelf life of IFA must remain at the time of receiving the shipment. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package.

Labelling:

The label on each strip of **IFA-WIFS** shall conform to the requirements of Rule 96 of Drugs & Cosmetic Rules and shall appear in English.

All labeling of **IFA-WIFS** should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Rule 96 of Drug & Cosmetic Rules, all labels shall state the amount of ferrous sulphate and equivalent amount of Ferrous iron & Folic Acid, the name of the manufacturer, manufacturing license number, address of manufacturer, batch number, and expiry date.

Labeling for secondary packaging:

A label of **IFA-WIFS** must be affixed either on the top and/or front surface of the secondary package. It should indicate the number of strips/tablets, the amount of ferrous sulphate and equivalent amount of Ferrous iron & Folic Acid, the name of **IFA-WIFS** drug manufacturer, batch number, date of manufacture, date of expiry, and storage conditions.

Labeling for tertiary packaging (insulated packaging):

The external surface of insulated packages should be either white or in the natural color of corrugated carton. The label should in both English and Hindi/local language of the State.

The labels of **IFA-WIFS** on tertiary packaging must be attached to at least two sides. The label should include the name of the product " **IFA-WIFS** " the number of secondary packages (boxes)/strips/tablets, the name of the manufacturer, batch number, date of manufacture, and date of expiry.

Numbering of tertiary packaging:

All boxes should be numbered consecutively. Shipping documents should be included in the box labeled number l.

Additional Labeling:

All the containers and other outer containers shall be marked with the statement "GOVT SUPPLY-NOT FOR SALE" in English and Local language.

All labels on containers i.e. strips, cartoons etc. should be marked with the statement "GOVT SUPPLY-NOT FOR SALE" in bold letters in English and local language.

B. QUALITY ASSURANCE

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per cGMP included in Schedule M of Drugs & Cosmetic Rules.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The Supplier shall provide the validation data of the analytical procedure used for assaying the components.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to / after the shipment of the product.

Testing:

The Purchaser may cause independent laboratory testing of the samples picked randomly from pre and post-delivery shipment to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on the product.

C. PACKING :

Primary Package:

15 Tablets should be packed in an Aluminium -Aluminium strip with **IFA-WIFS** name displayed prominently.

Aluminium Strips: Thickness of Aluminium Foil: 40 microns with LDPE 25 micron coating /heat seal lacquer.

- Toll free number must be indicated on every secondary package for contacting in case of product complaints.

Secondary Package:

The strips should be packaged in boxes for easy handling, transport and distribution with WIFS name displayed prominently. The box may contain 10 strips. It shall be fabricated from Millboard/ grey board/ card board with a minimum of bursting strength of 400 gsm.

- Toll free number must be indicated for contacting in case of product complaints.

Tertiary Package:

The boxes shall be packed in weather resistant triple walled insulated corrugated 5-ply cartons, each ply having strength of minimum 150 gsm with WIFS name displayed prominently. It should be fabricated from virgin quality "A" grade material. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.

- Toll free number must be indicated for contacting in case of product complaints.

D. QUALIFICATION OF THE MANUFACTURER:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to cGMP Standards and Schedule M of Drugs & Cosmetic Rules.

E. RECALLS:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged 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 quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

In case the quality of the product is found to be sub-standard or unsatisfactory in quality checks, stringent action would be taken against them and the supplier can be black-listed for future supplies of the product.

F. COLOUR CODING:

The Labels on secondary packing, tertiary packing and shipper package shall be identified by background. (Standard Pink Color).

G. BAR CODING:

Bar code shall be used to track down the product. It shall be printed on the label of Millboard/Grey board boxes and 5-Ply shipper containing

5. Product identification (GTIN 14) using application identifier (01)
6. Expiry date in YYMMDD format & using application identifier (17)
7. Master batch number using application identifier (10)
8. Bar coding to be put on all Tertiary and Secondary Packing.

Complete details on GSI standards along with technical guidelines can be downloaded from www.gs1india.org or www.gs1.org

iv. MARKINGS:

All containers and invoices must bear the **IFA-WIFS** name of the product, expiry dates of and appropriate storage conditions.

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Name IFA-WIFS
- Generic name of the product
- Manufacturer's name and registered address
- Manufacturer's License number
- Lot or batch number
- Number of strips contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling
- Place of manufacture
- Barcode

Exterior Shipping Cartons :

The following information shall be stenciled or labeled on the exterior shipping cartons on all four sides in bold letters at least **Ariel font size 14** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Name IFA – WIFS
- Generic name of the product
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)

- Manufacturer's name and registered address

Consignee's address and emergency phone number including mobile number

- Contract number
- Number of tablets/strips/boxes contained in the carton
- Gross weight of each carton (in kg)
- Carton containing no. of …. Secondary packages
- Instructions for storage and handling
- Place of manufacture
- Barcode

v. <u>Documentation:</u>

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be supplied must be sent at least seven days in advance of arrival of the consignment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) shall be intimated well in advance by registered letter/e-mail/telephone, so that the products are collected immediately after arrival.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB) if applicable;
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) as per the requirements issued by the Regulatory authority for each lot and
- Any other document, certificate or instruction specified in the individual order.

The documents shall be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages and gross weight(in Kilograms);
- Value of shipment(in Indian Rupees);
- A WB and Flight number(s) if applicable;
- Date and time for place of departure, transit (if applicable), and arrival;

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- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.
- Invoice

The following information shall be stated on the invoice:

- Consignee's name, address, telephone number (including mobile no.) and e-mail ID.
- Purchase order reference;
- Consignee's requisition reference;
- Instructions to:"Telephone consignee upon arrival (repeat telephone number);

vi. DISPATCH

Consignments should be scheduled to arrive outside weekends and/or public holidays.

Annexure IFA-WIFS

Additional tests: Ferrous Sulphate and Folic Acid Tablets

The method of analysis should be validated as per ICH guidelines

Seals Integrity Test:

Check 10strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Re-establish normal pressure and open strips to examine for water penetration

Microbial Count:

When the test is conducted as per IP

-Total viable aerobic count-Not more than 10^3 bacteria and not more than 10^2 fungi per gram

-Absence of Escherichia coli

15(C) ITEM CODE 448W- Ferrous Sulphate and Folic Acid Syrup

(For NCB)

A. SPECIFIC REQUIREMENTS

Item:

Iron and Folic acid Syrup shall conform to the requirements given IP 2014 under Iron & Folic Acid Syrup and the general requirements of Oral Liquids given in IP.

The drug shall be currently registered in India and shall meet all requirements of the licensing authorities of India.

Description:

Iron and Folic Acid Tablets (WIFS-JUNIOR) contain Ferrous Iron (derived from Ferrous Sulphate IP) and Folic Acid IP and a suitable anti-oxidant and antimicrobial agent in a suitable flavored vehicle . It is intended to be diluted well with water before use.

Each 1 ml of the syrup shall contain :

- Ferrous Iron (Derived from Ferrous sulphate IP) :20 mg
- Folic Acid IP 0.1 mg

The quality of each constituent should conform to the requirements of IP.

Protocol and Testing:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.

Protocols of tests should include the requirements given in IP 2014 under Iron & Folic Acid Tablets and the general requirements for Oral Liquids.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.

Each batch should be accompanied with a certificate from the manufacture that the drugs meet the specified requirements.

Random batches will be taken from the supplies of the State (post-delivery) and will be periodically tested (quarterly/six monthly) by DoHFW / MoHFW in identified labs separately for monitoring quality assurance.

Storage:

Iron and Folic Acid Syrup should be protected from light/moisture/rodents/damage to packaging. IFA Syrup should be stored in a cool and a dry place.

Shelf-life:

18 months, at least 3/4th of the shelf life of IFA must remain at the time of receiving the shipment. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package.

Labelling:

The label on each Bottle shall be map litho paper with minimum 300 gsm. The lable shall conform to the requirements of IP & Rule 96 of Drugs & Cosmetic Rules and shall appear in the language of English.

All labeling of IFA syrup should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Rule 96 of Drug & Cosmetic Rules, all labels shall state the amount of ferrous sulphate and equivalent amount of Ferrous iron & Folic Acid, name of the anti-oxidant and antimicrobial agent, the name of the manufacturer, manufacturing license number, address of manufacturer, batch number, and expiry date.

If an artificial sweeteining is used, it should be highlighted on the label . Besides, having the flavouring agent used should be of food grade.

A Warning should be put on the label that 'Medication should be kept out of reach of children. '

The Bottle should have 6 fragmented marking at equal intervals as the entire content (50 ml) has to be consumed in 6 months and the consumption compliance can be verified. The marking can be either embossed on the bottle or printed on the labeling paper stuck on the bottle.

Labelling sticker should have a box space for writing the name of the child on the bottle.

Labelling should clearly indicate :

1. 'For children 6-59 months.'
2. Dosage 1 ml
3. Must be given orally after the meal – not to be given empty stomach
4. IFA syrup bottle should be stored in a cool and dry place and away from sunlight.

Labeling for secondary packaging:

A label of IFA SYRUP must be affixed either on the top and/or front surface of the secondary package. It should indicate the number of bottles, the amount of ferrous sulphate and equivalent amount of Ferrous iron & Folic Acid, the name of

manufacturer, batch number, date of manufacture, date of expiry, and storage conditions. The label should in both English and Hindi / local language of the state.

Labeling for tertiary packaging (insulated packaging):

The external surface of insulated packages should be either white or in the natural color of corrugated carton.

The labels of IFA SYRUP on tertiary packaging must be attached to at least two sides. The label should include the name of the product "IFA SYRUP " the number of secondary packages (boxes)/strips/tablets, the name of the manufacturer, batch number, date of manufacture, and date of expiry.

Numbering of tertiary packaging:

All boxes should be numbered consecutively. Shipping documents should be included in the box labeled number l.

Additional Labeling:

All the containers and other outer containers shall be marked with the statement "GOVT SUPPLY-NOT FOR SALE" in English and Local language.

All labels on containers i.e. strips, cartoons etc. should be marked with the statement "GOVT SUPPLY-NOT FOR SALE" in bold letters in English and local language.

B. QUALITY ASSURANCE

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per cGMP included in Schedule M of Drugs & Cosmetic Rules.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The Supplier shall provide the validation data of the analytical procedure used for assaying the components.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

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Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to / after the shipment of the product.

Testing:

The Purchaser may cause independent laboratory testing of the samples picked randomly from pre and post-delivery shipment to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on the product.

C. PACKING :

Primary Package:

Iron and Folic acid Syrup shall be packed in 50 ml capacity Pharmaceutical grade polyethylene terephthalate amber coloured bottles (AA8011 / AA 1200); and provided with temper evident ROPP cap (25/15mm or 25/17mm). The cap should be provided with inert liner. The bottle is to be provided with a auto dispenser 1 ml each time and packed in mono carton. The plastic cap – cum – orifice that release syrup must be firmly attached to the bottle so that it is impossible for the child to accidently swallow the entire content.

- The mono carton should also contain a 1 pager instruction leaflet in local language Hindi. *(Draft-annexed below as **Annexure : leaflet)***

- Toll free number must be indicated on every secondary package for contacting in case of product complaints.

Secondary Package:

The bottles should be packed in boxes for easy handling, transport and distriction from 3-ply corrugated cardboard having strength $(150)^3$ gsm.

- Toll free number must be indicated for contacting in case of product complaints.

Tertiary Package:

The boxes shall be packed in weather resistant triple walled insulated corrugated 7-ply cartons, usually containing 10 secondary packages having sufficient burst strength to hold weight of 100 bottles. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.

- Toll free number must be indicated for contacting in case of product complaints.

D. QUALIFICATION OF THE MANUFACTURER:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to cGMP Standards and Schedule M of Drugs & Cosmetic Rules.

E. RECALLS:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged 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 quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

In case the quality of the product is found to be sub-standard or unsatisfactory in quality checks, stringent action would be taken against them and the supplier can be black-listed for future supplies of the product.

F. COLOUR CODING:

The Labels on secondary packing, tertiary packing and shipper package shall be identified by background. (Standard RED Color).

G. BAR CODING:

Bar code shall be used to track down the product. It shall be printed on the label of Millboard/Grey board boxes and 5-Ply shipper containing

9. Product identification (GTIN 14) using application identifier (01)
10. Expiry date in YYMMDD format & using application identifier (17)
11. Master batch number using application identifier (10)

Complete details on GSI standards along with technical guidelines can be downloaded from www.gs1india.org or www.gs1.org

12. Bar coding to be put on all Tertiary and Secondary Packing.

H. MARKINGS:

All containers and invoices must bear the IFA SYRUP name of the product, expiry dates of and appropriate storage conditions.

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Name IFA SYRUP

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- Generic name of the product
- Manufacturer's name and registered address
- Manufacturer's License number
- Lot or batch number
- Number of strips contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling
- Place of manufacture
- Barcode

Exterior Shipping Cartons :

The following information shall be stenciled or labeled on the exterior shipping cartons on all four sides in bold letters at least **Ariel font size 14** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Name IFA SYRUP
- Generic name of the product
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)
- Manufacturer's name and registered address
  Consignee's address and emergency phone number including mobile number
- Contract number
- Number of tablets/strips/boxes contained in the carton
- Gross weight of each carton (in kg)
- Carton containing no. of …. Secondary packages
- Instructions for storage and handling
- Place of manufacture
- Barcode

I. <u>Documentation:</u>

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be supplied must be sent at least seven days in advance of arrival of the consignment. In the case of an individual contract for a

specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) shall be intimated well in advance by registered letter/e-mail/telephone, so that the products are collected immediately after arrival.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB) if applicable;
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) as per the requirements issued by the Regulatory authority for each lot and
- Any other document, certificate or instruction specified in the individual order.

The documents shall be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages and gross weight(in Kilograms);
- Value of shipment(in Indian Rupees);
- A WB and Flight number(s) if applicable;
- Date and time for place of departure, transit (if applicable), and arrival;
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.
- Invoice

The following information shall be stated on the invoice:

- Consignee's name, address, telephone number (including mobile no.) and e-mail ID.
- Purchase order reference;
- Consignee's requisition reference;
- Instructions to:"Telephone consignee upon arrival (repeat telephone number);

J. <u>DISPATCH</u>

Consignments should be scheduled to arrive outside weekends and/or public holidays.

Annexure: leaflet
[Ref. to Clause 15(C)(C)]

दवा (IFA Syrup) सम्बन्धी महत्वपूर्ण जानकारी

इस दवा (IFA Syrup) के कुछ सामान्य प्रश्नों के उत्तर इस पत्रक द्वारा प्राप्त होंगे। ये डॉक्टर, ANM या ASHA से बात करने की महत्ता की जगह नहीं लेता। इस दवा को बच्चे को देने से पहले कृपया इस पत्रक को ध्यान से पढें। यदि इस दवा के बारे में आपके मन में कोई भी सवाल हैं तो कृपया नजदीकी डॉक्टर, ANM या ASHA से पूछे। इस पत्रक को आप अपनी दवाई के साथ रखे, शायद इसे दुबारा पढ़ना पढ़े।

- **यह दवा (IFA Syrup) किसके लिए ?**

6–59 माह की उम्र के सभी बच्चों को यह दवा देनी चाहिए। एनीमिया की रोकथाम के लिए प्रत्येक बच्चे को यह दवा नियमित देनी चाहिए। एनीमिया से पीड़ित बच्चों के लिए डॉक्टर, ANM या ASHA की सलाह पर आवश्यकता से अधिक दवा देने की सलाह भी दी जा सकती हैं।

- **दवा : कितनी मात्रा में दी जानी हैं ?**

1 मि.ली. – सप्ताह में दो बार जैसे सोमवार एवं गुरूवार, मंगलवार एवं शुक्रवार आदि।

- **इस दवा (IFA Syrup) का उपभोग से क्या लाभ हो सकता हैं ? दवा को सप्ताह में दो बार लेने के लाभ :–**
  - ❖ यह दवा (IFA Syrup), लौह की कमी से होने वाले एनीमिया की रोकथाम और उसके इलाज के लिए iron और folic acid का एक साधन हैं। Iron और Folic acid बच्चे के शारीरिक, मानसिक, ज्ञानात्मक और प्रजनन स्वास्थ्य के लिए महत्वपूर्ण होता हैं।
  - ❖ लौह की कमी से होने पर एनीमिया पीड़ित बच्चों में थकावट, कम सक्रिय, कम ज्ञानात्मक विकास औंर विद्यालय में कार्यशीलता कम हो जाती हैं।
  - ❖ 1मि.ली. दवा सप्ताह में दो बार लेने से बच्चें के स्वास्थ्य में सुधार, सक्रियता एवं पढ़ाई में एकाग्रता औंर बच्चें की समझदारी बढ़ती हैं।
  - ❖ बच्चें क्रियाशील, सतर्क बनते हैं एवं जल्दी थकते नहीं हैं।
- **इस दवा (IFA Syrup) को किस किसको पिलाना चाहिए ?**
  - ❖ 6–59 माह की उम्र के बच्चों को उनकी माताओं या उनके परिवार के वयस्कों के द्वारा पिलाना चाहिए।
  - ❖ 1मिली दवा (IFA Syrup) देने की तकनीक ASHA/ANM या डाक्टॅर से सीखे।
- **इस दवा (IFA Syrup) को कब पिलावे ?**
  - ❖ दवा बच्चें को खाली पेट नहीं देनी चाहिए।

- ❖ दवा बच्चें को तब ही देवे जब कम से कम आधी कटोरी खाना खाया हो, सामान्यतः स्तनपान या रात के खाने के बाद ही दी जानी चाहिए।
- ❖ दवा देने के साथ–साथ खाने में बच्चों को लौह तत्व बढ़ाने वाले पदार्थ जो आसानी से पचाए जा सके वो देने चाहिए। लौह बढ़ाने वाले तत्व विटामिन सी से भरे खानें में होता हैं जैसे नींबू, अमरूद, आंवला, नारंगी, किण्वित या अंकुरित खाना आदि।

- **बच्चें को दवा देने से पहले डॉक्टर से सलाह लेवे, यदि :–**
  - ❖ बच्चा बीमार हैं (उदाहरणतः बुखार होना, डॉयरिया, निमोनिया, मलेरिया आदि।)
  - ❖ बच्चें को किसी दवा से रिएक्शन या एलर्जी (दुष्प्रभाव) है तो।
  - ❖ बच्चा गम्भीर कुपोषण से पीड़ित हैं तो। (इसके बारे में ASHA के द्वारा बताया जाएगा)। बच्चें को खून चढ़ाया (Blood Transfusion) जा रहा हो।
- **बच्चें को दवा नहीं पिलावे, यदि –**
  - ❖ दवा की शीशी को देने की अन्तिम तिथि (expiry date) निकल जाने पर या दवा में कुछ गड़बड़ी होने का अंदेशा हो।
- **कृपया घबराऐं नहीं यदि :–**
  - ❖ कुछ बच्चों में दवा के कारण जी मिचलाना, पेट की परेशानी, दस्त, कब्ज आदि हो सकते हैं। ये मंद नुकसान सामान्यतः अस्थाई होते हैं और बच्चें के शरीर में दवाईयों के प्रति अनुकूलन होने लगता हैं जिससे इनका प्रभाव गायब होने लगता हैं।
  - ❖ यदि ऐसा कोई प्रभाव निरन्तर रहता है, तो आप ASHA/ ANM या डॉक्टर को सम्पर्क कर।
  - ❖ सामान्यतः आयरन युक्त दवाईयों के कारण टट्टी का रंग काला होता है परन्तु यह नुकसानदायक नहीं होता, इसलिए अपने बच्चे की काली टट्टी को देखकर चिन्ता न करे।
  - ❖ इन संभावित दुष्प्रभावों की सूची देखकर चिंतित न हो।
- **इस दवा को कैसे सुरक्षित रखे। :–**
  - ❖ दवा की शीशी को अपने बच्चों से दूर रखें, उसकी आवश्यकता से अधिक खुराक बच्चें के लिए नुकसानदेह हो सकती हैं।
  - ❖ दवा की शीशी ठण्डी और सूखी जगह पर रखे और सूर्य की रोशनी से दूर रखे।
  - ❖ दवा की शीशी को गुसलखाने/स्नानघर में, सिंक के पास या खिड़की के पास न रखे।
  - ❖ दवा की शीशी के ढ़क्कन को दवा पिलाने के बाद कस के (tightly) बंद करे।

16. QUALITY TESTING

1. Sampling of supplies from each batch will be done at the point of supply or distribution/storage points for testing. (The samples would be sent to different empanelled laboratories for testing by the ordering authority after coding). The RMSC will deduct a sum of 1.5% from the amount of bill payable to supplier on account of handling and testing charges.
2. The Drugs shall have the active ingredients within the permissible level throughout the shelf life period of the drug. The samples may also be drawn periodically during the shelf life period. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. Samples which do not meet quality requirements shall render the relevant batches liable to be rejected. If the sample is declared to be Not of Standard Quality or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods.
3. In the event of the samples of the Drugs and medicines supplied failing quality tests or found to be not as per specification the ordering authority is at liberty to make alternative purchase of items of drugs and medicines for which the Purchase orders have been placed from any other sources or from the open market or from any other Bidder who might have quoted higher rates at the risk and the cost of the supplier and in such cases the ordering authority has every right to recover the cost and impose penalty as mentioned in Clause 19.
4. The supplier shall furnish to the purchaser the evidence of bio-availability and/or bio-equivalence for certain critical drugs when asked for. If there is any problem in the field the B.M.R/B.P.R for the particular batch shall also be supplied when demanded.
5. The products should conform to the standards of IP/BP / USP as the case may be. In case the product is not included in the said compendium, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing. For imported drugs respective countries pharmacopeia standards shall be acceptable (even if the product is official in IP)
6. ***The supply of any item shall be considered complete for the purpose of calculation of liquidated damages only when reference standards/ standard***

testing procedure or test protocol/placebo materials are made available to the corporation along with the supply of items as per the purchase order. However these materials and documents shall be made available by supplier to Quality Cell of RMSC Headquarter. Such requirement will however be indicated in the purchase order.

17. <u>PAYMENT PROVISIONS</u>

1. No advance payment towards costs of drugs, medicines etc., will be made to the Bidder.
2. On receipt of the prescribed consolidated invoice duly stamped and signed by authorized signatory and analytical laboratory report regarding quality, the payment would be made in 30 days. (Annexure- XII & XIII)
3. The in charge of district drug warehouse (DDW) will acknowledge the drugs received & ensure entry in e- Aushadhi software online. .
4. All bills/ Invoices should be raised in duplicate and in the case of excisable Drugs and Medicines; the bills should be drawn as per Central Excise Rules in the name of the authority as may be designated. The supplier will deliver following document at the time of delivery at DDW.
    a. In house test report of drug.
    b. The challan / invoice copy pertaining to DDW
5. Payments for supplies will be considered after receipt of reports of standard quality on samples having been tested approved laboratories of ordering authority. Furthermore, in case the supplies do not meet the ordered quantities, following condition shall apply.

(i) If a bidder fails to supply the complete quantity (but has supplied at least 70%) of an item ordered in the Purchase Order, a penalty @ 10% of the value of unsupplied/short supplied quantity, shall be levied. ***The minimum penalty shall be Rs 1000/- in case if it comes to less than this amount by calculation.***

(ii) If a bidder fails to supply even 70% of the quantity of an item ordered in the Purchase Order, an extra penalty @ 2% in Purchase Order value shall be levied in addition to the penalty referred to in Para 17(5) (i) above.

6. If at any time during the period of contract, the price of Bided items is reduced or brought down by any law or Act of the Central or State Government or by the

Bidder himself, the Bidder shall be bound to inform ordering authority immediately about it. Ordering authority empowered to unilaterally effect such reduction as is necessary in rates in case the Bidder fails to notify or fails to agree for such reduction of rates.

In case the price of a drug fixed by NPPA (Govt of India) under applicable DPCO is less than the RMSC contract price, the supplier shall be bound to make the supplies of such items at price fixed by the Govt.

7(a) In case of any enhancement in Excise Duty due to notification of the Government after the date of submission of Bids and during the Bid period, the quantum of additional excise duty so levied will be allowed to be charged extra as a separate item without any change in the basic of the price structure price of the Drugs approved under the Bid. For claiming the additional cost on account of the increase in Excise Duty, the Bidder should produce a letter from the concerned Excise authorities for having paid additional Excise Duty on the goods supplied to ordering authority and also must claim the same in the invoice separately.

Similarly if there is any reduction in the rate of essential drug, as notified by the Govt., after the date of submission of Bid, the quantum of the price to the extent of reduction of essential drug will be deducted without any change in the basic price of the price structure of the drugs approved under the Bid.

7(b) In case of successful bidder has been enjoying excise duty exemption on any criteria of Turnover etc., such bidder will not be allowed to claim excise duty at later point of time, during the tenure of contract, when the excise duty is chargeable on goods manufactured.

8. (i) If the supplier requires an extension in time for completion of contractual supply, on account of occurrence of any hindrance he shall apply in writing for extension on occurrence of hindrance but not after the stipulated date of completion of supply.

(ii) The purchase Officer may extend the delivery period with or without liquidated damages in case they are satisfied that the delay in the supply of goods is on account of hindrances. Reasons shall be recorded.

(iii) **Extension in delivery period:-** In case of extension in the delivery period with liquidated damages the recovery shall be made on the basis of following percentages of value of stores which the Bidder has failed to supply:-

a) Delay upto one fourth period of the prescribed delivery period; 2.5%
b) Delay exceeding one fourth but not exceeding half of the prescribed delivery period; 5%
c) Delay exceeding half but not exceeding three fourth of the prescribed delivery period; 7.5%
d) Delay exceeding three fourth of the prescribed delivery period; 10%

Note 1:- ***Fraction of a day in reckoning period of delay in supplies shall be eliminated if it is less than half a day. The maximum amount of liquidated damages shall be 10%.***

Note 2: ***In specific condition, permission for additional delay of 10 days may be granted for supply, in such a case an additional penalty of 5% shall be levied.***

Note 3:- ***If a supplier seeks extension in supply period beyond two times the time indicated in purchase order, the supply period shall be extended with the condition that if the rate received in new bid(s) invited are lower than the rate contract in operation, then the supplier shall be entitled to the lower rates so received.***

9. If, at any time during the continuance of this Agreement, the Supplier has, in the opinion of the Purchaser, delayed in making any supply ordered, by the reasons of any riots, mutinies, ears, fire, storm, tempest or other exceptional cause, on a specific request made by the Supplier, the time for effecting delivery may be extended by the Purchaser surely at his discretion for such period as may be considered reasonable by the Purchaser. No further representation from the Supplier will be entertained on this account.

10. If the firm is Blacklisted/Debarred by State Govt. of Rajasthan during rate contract period/ after rate contract period, the firm has to follow below mentioned conditions:-

- **Further Purchase orders should not be placed to firm.**
- **Purchase orders in process shall be cancelled.**
- **All unconsumed stock from DDWs should be lifted on the cost of firm.**

- **If payment is made for unconsumed stock it should be recovered from firm.**
- **All rate contracts should be cancelled.**

18. DEDUCTION IN PAYMENTS:

1. If the supply is received in damaged conditions it shall not be accepted.
2. All the Bidder are required to supply the product with logogram and with prescribed packing specification. If there is any deviation in these Bid conditions a separate damages will be levied @ 2% irrespective of the ordering authority having actually suffered any damage/loss or not, without prejudice the rights of alternative purchase specified in Clause **No.15.10.**

19. QUALITY CONTROL DEDUCTION & OTHER PENALTIES:

1. If the successful Bidder fails to execute the agreement and/or to deposit the required performance security within the time specified or withdraws his Bid after the intimation of the acceptance of his Bid has been sent to him or owing to any other reasons, he is unable to undertake the contract, his contract will be cancelled and the Bid security Deposit deposited by him along with his Bid, shall stand forfeited by the Bid Inviting Authority and he will also be liable for all damages sustained by the Bid Inviting Authority apart from **blacklisting/ debarring the supplier.** (As per guidelines for blacklisting/ debarring at annexure IX including amendment)
2. If the samples drawn from supplies do not conform to statutory standards, the supplier will be liable for relevant action under the existing laws and the entire stock in such batch should be taken back by the supplier within a period of 30 days from the issue of letter from ordering authority the information of which may be communicated by e- mail. The stock shall be taken back at the expense of the supplier. Ordering authority has the right to destroy such NOT OF STANDARD DRUGS IF THE SUPPLIER does not take back the goods within the stipulated time. Ordering authority will arrange to destroy the NOT OF STANDARD drugs within 90 days after the expiry of 30 days mentioned above, without further notice, and shall also collect demurrage charge calculated @ 2% per week on the value of the drugs rejected till such destruction.

   The Supplier shall replace the stock of NOSQ goods with fresh goods upon intimation to do so by the ordering authority.

3. The supplier will not be entitled to any payment whatsoever for Items of drugs found to be of NOT OF STANDARD QUALITY whether consumed or not consumed and the ordering authority is entitled to deduct the cost of such batch of drugs from the any amount payable to the Bidder. On the basis of nature of failure, the product/supplier will be moved for Black Listing. (As per guidelines for blacklisting/ debarring at annexure IX including amendment)
4. For supply of drugs of NOT OF STANDARD QUALITY the respective Drugs Controller will be informed for initiating necessary action on the supplier and that the report of product shall be sent to the committee for appropriate action including blacklisting. (As per guidelines for blacklisting/ debarring at annexure IX including amendment)
5. The decision of the ordering authority or any Officer authorized by him as to the quality of the supplied drugs, medicines etc., shall be final and binding.
6. Ordering Authority will be at liberty to terminate without assigning any reasons thereof the contract either wholly or in part on 30 days notice. The Bidder will not be entitled for any compensation whatsoever in respect of such termination.
7. For infringement of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the ordering authority, and the supplier shall be liable for all losses sustained by the ordering authority, in consequence of the termination which may be recovered personally from the supplier or from his properties, as per rules.
8. Non performance of any contract provisions shall be examine and may disqualify the firm to participate in the future Bids.
9. In the event of making ALTERNATIVE PURCHASE, as specified in Clause **13.10, Clause 15.10 and in Clause 16.3** the penalty will be imposed on supplier apart from forfeiture of Security Deposit. The excess expenditure over and above contracted process incurred by the ordering authority in making such purchases from any other sources or from the open market or from any other Bidder who has quoted higher rates and other losses sustained in the process, shall be recovered from the performance security or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier ***and provided further***

that such amount to be levied as per penalty form supplier on account of non-supply shall not be less than 10% of the value of non-supplied even when rates in alternative purchase method are lower / equivalent to rates in original tender..

10. In all the above conditions, the decision of the Bid Inviting Authority, viz Managing Director, Rajasthan Medical Services Corporation Ltd, would be final and binding; in case of any dispute regarding all cases under Bid procedure or in any other non-ordinary situation and would be acceptable to all.
11. All litigations related to the supplier for any defaults will be done by Bid Inviting Authority and his decision will be final and binding.
12. **In the case of litigation as per court decision/award by arbitrator, if any amount of interest is payable/receivable etc. then RMSC will charge interest@9% per annum simple interest and it will be payable @ 6% per annum simple interest only.**

20. **EMPANELMENT OF FIRMS**

RMSC invites Applications from eligible firms for Empanelment for supply of Drugs & Medicines mentioned in Annexure- VIII for one year. The empanelment would entitle a firm to participate in RMSC for limited bids. Such situations may normally arise when the open bid for a Drugs & Medicines fails and there is an urgency to purchase it, or when the L-1 bidder has fail to supply, or the rate contract of an item ceases to exist for any reason. The Bidder has to submit an undertaking in the format given at Annexure-XI.

The empanelment can be renewed for the next one year term on payment of the empanelment fee as applicable at the time of renewal.

21. SAVING CLAUSE

No suit, prosecution or any legal proceedings shall lie against Bid Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of Bid.

22. JURISDICTION

In the event of any dispute arising out of the Bid or orders such dispute would be subject to the jurisdiction of the Courts of Jaipur or Honorable High Court (Jaipur Bench **only**).

23. CORRECTION OF ARITHMETIC ERRORS:

Provided that a financial bid is substantially responsive, the procuring Entity will correct arithmetical errors during evaluation of Financial Bids on the following basis:

(i) 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 price shall prevail and the total price shall be corrected, unless in the opinion of the Procuring Entity there is an obvious misplacement of the decimal point in the unit price, in which case the total price as quoted shall govern and the unit price shall be corrected;

(ii) If there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and.

(iii) If there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to clause (a) and (b) above.

If the Bidder that submitted the lowest evaluated bid does not accept the correction of errors, its Bid shall be disqualified and its Bid Security shall be forfeited or its Bid Securing Declaration shall be executed.

24. PROCURING ENTITY'S RIGHT TO VARY QUANTITY:

(i) At the time of award of contract, the quantity of Drugs, originally specified in the bidding documents may be increased or decreased. There will not be any minimum quantity guaranteed against bid quantity. The bid quantity is only indicative. Actual purchase can be more or less than the bid quantity based on actual consumption in the hospitals during Rate Contract period.

The supplier shall submit the supply commitment quantity'' in Annexure **VII at point no. 3** which will be used for the cases where the actual purchase quantity tends to increase substantially from the bid quantity.

(ii) If the procuring entity does not procure any subject matter of procurement or procures less than the quantity specified in the bidding documents due to change in circumstances, the bidder shall not be entitled for any claim or compensation except otherwise provided in the conditions of contract.

(iii) However a bidder is bound to supply up to quantity indicated in bid document, considering the total production capacity & capacity dedicated to RMSC. Moreover, the actual purchases beyond Bid quantity may be made keeping in view the supply commitment of bidder to corporation.

25. DIVIDING QUANTITIES AMONG MORE THAN ONE BIDDER AT (IN CASE OF PROCUREMENT OF GOODS):

The orders may split between L-1 and rate matched firms. Quantities may be divided between L1 and matched L1 as 80:20. In case L2 and L3 match L1 than quantities may be divided as 75:15:10. Whenever L2 or L3 firms are more one, then quantity would be distributed equally.

26. GRIEVANCE REDRESSAL DURING PROCUREMENT PROCESS:

The Designation and address of the First Appellate Authority is ***Special Secretary /*** Secretary, Medical, Health & Family Welfare, Govt. of Rajasthan.

The Designation and address of the Second Appellate Authority is Principal Secretary, Medical, Health & Family Welfare, Govt. of Rajasthan and Chairman, RMSCL.

i. Filling an appeal

If any Bidder or prospective bidder is aggrieved that any decision, action or omission of the Procuring Entity is in contravention to the provisions of the Act or the Rules of the Guidelines issued there under, he may file an appeal to First Appellate Authority, as specified in the Bidding Document within a period of ten days from the date of such decision or action, omission, as the case may be, clearly giving the specific ground or ground on which he feels aggrieved:

Provided that after the declaration of a Bidder as successful the appeal may be filed only by a Bidder who has participated in procurement proceedings:

Provided further that in case a Procuring Entity evaluates the Technical Bids before the opening of the Financial Bids, an appeal related to the matter of Financial Bids may be filed only by a Bidder whose Technical Bid is found to be acceptable.

ii. The Officer to whom an appeal is filed under Para (1) shall deal with the appeal as expeditiously as possible and shall Endeavour to dispose it of within thirty days from the date of the appeal.

iii. If the officer designated under Para (1) fails to dispose of the appeal filed within the period specified in Para (2), or if the Bidder or prospective bidder or the Procuring Entity is aggrieved by the order passed by the First Appellate Authority, the Bidder or prospective bidder or the Procuring Entity, as the case may be, may file a second appeal to second Appellate Authority specified in the Bidding Document in this behalf within fifteen days from the expiry of the period specified in Para (2) or of the date of receipt of the order passed by the First Appellate Authority, as the case may be.

iv. Appeal not to lie in certain cases

No appeal shall lie against any decision of the Procuring Entity relating to the following matters, namely:-

(a) Determination of need of procurement;

(b) Provision limiting participation of Bidders in the Bid process; (c) The decision of whether or not to enter into negotiations;

(d) Cancellation of a procurement process;

(e) Applicability of the provisions of confidentiality.

v. Form of Appeal

(a) An appeal under Para (1) or (3) above shall be in the annexed Form along with as many copies as there are respondents in the appeal.

(b) Every appeal shall be accompanied by an order appealed against, if any, affidavit verifying the facts stated in the appeal and proof of payment of fee.

(c) Every appeal may be presented to First Appellate Authority or Second Appellate Authority, as the case may be, in person or through registered post or authorised representative.

vi. Fee for filling appeal

(a) Fee for first appeal shall be rupees two thousand five hundred and for second appeal shall be rupees ten thousand, which shall be non-refundable.

(b) The fee shall be paid in the form of bank demand draft or banker's cheque of a Scheduled Bank in India payable in the name of Appellate Authority concerned.

vii. Procedure for disposal of appeal

(a) The First Appellate Authority or Second Appellate Authority, as the case may be, upon filling of appeal, shall issue notice accompanied by copy of appeal, affidavit and documents, if any, to the respondents and fix date of hearing.

(b) On the date fixed for hearing, the First Appellate Authority or Second Appellate

Authority, as the case may be, shall,-

(i) Hear all the parties to appeal present before him; and

(ii) Peruse or inspect documents, relevant records or copies thereof relating to the matter.

(c) After hearing the parties, perusal or inspection of documents and relevant records or copies thereof relating to the matter, the Appellate Authority concerned shall pass an order in writing and provide the copy of order to the parties free of cost.

(d) The order passed under sub-clause (c) above shall be placed on the State Public procurement Portal.

27. <u>COMPLIANCE WITH THE CODE OF INTEGRITY AND NO CONFLICT OF INTEREST:</u>

Any person participating in a procurement process shall-

a) Not offer any bribe, reward or gift or any material benefit either directly or indirectly in exchange for an unfair advantage in procurement process or to otherwise influence the procurement process;

b) Not misrepresent or omit misleads or attempts to mislead so as to obtain a financial or other benefit or avoid an obligation;

c) Not indulge in any collusion, Bid rigging or any-competitive behaviour to impair the transparency, fairness and progress of the procurement process;

d) Not misuse any information shared between the procuring Entity and the Bidders with an intent to gain unfair advantage in the procurement process;

e) Not indulge in any coercion including impairing or harming or threatening to do the same, directly or indirectly, to any part or to its property to influence the procurement process;

f) Not obstruct any investigation or audit of a procurement process;

g) Disclose conflict of interest, if any; and

h) Disclose any previous transgressions with any Entity in India or any other country during the last three years or any debarment by any other procuring entity.

Conflict of interest:-

The Bidder participating in a bidding process must not have a Conflict of Interest.

A Conflict of interest is considered to be a situation in which a party has interests that could improperly influence that party's performance of official duties or responsibilities, contractual obligations, or compliance with applicable laws and regulations.

I. A Bidder may be considered to be in Conflict of interest with one or more parties in bidding process if, including but not limited to:

a. Have controlling partners/shareholders in common; or

b. Receive or have received any direct or indirect subsidy from any of them; or

c. Have the same legal representative for purposes of the Bid; or

d. Have a relationship with each other, directly or through common third parties, that puts them in a position to have access to information about or influence on the Bid of another Bidder, or influence the decisions of the Procuring Entity regarding the bidding process; or

e. The Bidder participates in more than one Bid in a bidding process. Participation by a Bidder in more than one Bid will result in the disqualification of all Bids in which the Bidder is involved. However, this

does not limit the inclusion of the same subcontractor, not otherwise participating as a Bidder, in more than one Bid; or

f. The Bidder or any of its affiliates participated as a consultant in the preparation of the design or technical specification of the Goods, Works or Services that are the subject of the Bid; or

g. Bidder or any of its affiliates has been hired (or is proposed to be hired0 by the Procuring Entity as engineer-in0chage/ consultant for the contract.

28. FALL CLAUSE

The prices under a rate contract shall be subject to price fall clause. If the rate contract holder quotes / reduces its price to render similar goods, works or services at a price lower than the rate contract price to anyone in the State at any time during the currency of the rate contract, the rate contract price shall be automatically reduced with effect from the date of reducing or quoting lower price, for all delivery of the subject matter of procurement under that rate contract and the rate contract shall be amended accordingly. The firms holding parallel rate contracts shall also be given opportunity to reduce their price by notifying them the reduced price giving them fifteen days time to intimate their acceptance to the revised price. Similarly, if a parallel rate contract holding firm reduces its price during currency of the rate contract, its reduced price shall be conveyed to other parallel rate contract holding firms and the original rate contract holding firm for corresponding reduction in their prices. If any rate contract holding firm does not agree to the reduced price, further transaction with it, shall not be conducted.

Managing Director
Rajasthan Medical Services Corporation

ANNEXURE-I

Annexure - 1

CAUTION : USE "FCMBR" MENU OPTION IN FINACLE INSTEAD OF "TM"

Bank Copy

punjab national bank

DIST. NO.

Branch

Institute Name: Rajasthan Medical Services Corporation, Jaipur

Institute ID: RMSCJ - A/c No. 2246002100024414

Date of Deposit: DD MM YY

DETAILS OF THE SUPPLIER

Supplier Name

Tender Ref. No.

Type of Deposit: Select any one out of - Tender Fees/EMD/SD/Tender Processing fees/Others

Mobile No.

Cash Deposit:

Denomination	₹	Ps
1000 *		
500 *		
100 *		
50 *		
20 *		
10 *		
5 *		
Coins *		
Total		

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹

Commission ₹ 0 0 0 0 0 - 0 0

Total amount ₹ -

Amount (in words): ₹ _____

Name of the Depositor

Signature

Address for communication

For Bank use only

Acknowledgement

Cashier/Officer

Customer Copy

punjab national bank

DIST. NO.

Branch

Institute Name: Rajasthan Medical Services Corporation, Jaipur

Institute ID: RMSCJ - A/c No. 2246002100024414

Date of Deposit: DD MM YY

DETAILS OF THE SUPPLIER

Supplier Name

Tender Ref. No.

Type of Deposit: Select any one out of - Tender Fees/EMD/SD/ Tender Processing fees/Others

Mobile No.

Cash Deposit:

Denomination	₹	Ps
1000 *		
500 *		
100 *		
50 *		
20 *		
10 *		
5 *		
Coins *		
Total		

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹

Commission ₹ 0 0 0 0 0 - 0 0

Total amount ₹ -

Amount (in words): ₹ _____

Name of the Depositor

Signature

Address for communication

For Bank use only

Acknowledgement

Cashier/Officer

-

ANNEXURE-II
Ref. Clause No.8

Format of Affidavit
(On Non Judicial Stamp Paper of Rs. 10/-)

I……S/o…….Age……..Yrs……. residing at……Proprietor/Partner/Director of M/s……do hereby solemnly affirm and declare that:

(a) My/Our above noted enterprises M/s…… has been issued acknowledgement of Entrepreneurial Memorandum Part-II by the Districts Industries Center……The acknowledgement No. is…….dated…….and has issued for Manufacture of following items.

(i)
(ii)
(iii)
(iv)
(v)

(b) My/Our above noted acknowledgement of Entrepreneurial Memorandum Part-II has not been cancelled or withdrawn by the Industries Department and that the enterprise is regularly manufacturing the above items.

(c) My/Our enterprise is having all the requisite plant and machinery and is fully equipped to manufacture the above noted items.

Place…….

Signature of Proprietor/Director
Authorized Signatory with Rubber Stamp and date

VERIFICATION

I……S/o…….Aged…….Yrs …….residing at……Proprietor/Partner/Director of M/s……verify and confirm that the contents at (a), (b) & (c) above are true and correct to the best of my knowledge and nothing has been concealed therein. So help me God.

DEPONENT

-

ANNEXURE-III
Ref. Clause No. 5 (m)

ANNUAL TURN OVER STATEMENT

The Annual Turnover ***(for drugs and medicines including Surgical and sutures Business)*** of M/s._____for the past three years are given below and certified that the statement is true and correct.

S.No.	Years	Turnover in Lakhs (Rs)
1	2012-13	
2	2013-14	
3	2014-15	
Total		**Rs.** **Lakhs**
Average turnover per annual		**Rs.** **Lakhs**

Or

S.No.	Years	Turnover in Lakhs (Rs)
1	2013-14	
2	2014-15	
3	2015-16	
Total		**Rs.** **Lakhs**
Average turnover per annual		**Rs.** **Lakhs**

Date:

Seal:

Signature of Auditor/
Chartered Accountant
(Name in Capital)

-

ANNEXURE-IV
Ref. Clause No.12(a)

AGREEMENT

This Deed of Agreement is made on this _____day of _____2016 by M/s._____ represented by its Proprietor/Managing partner/Managing Director having its Registered Office at _____and its Factory Premises at _____

(hereinafter referred to as "Supplier" which term shall include its successors, representatives, heirs, executors and administrators unless excluded by the Contract) on one part and Rajasthan Medical Services Corporation Ltd, represented by its Executive Director (P) having is office at Swasthya Bhawan, Tilak Marg, C-Scheme, Jaipur (hereinafter referred to as "The Purchaser" which term shall include its successors, representatives, executors assigns and administrator unless excluded by the Contract) on the other part.

Where as the Supplier has agreed to supply to the Purchaser, the Drugs and Medicines with specifications mentioned in the Schedule attached here to at the prices noted there in and in the manner and under the terms and conditions here in after mentioned and where as the Supplier has deposited with the Purchaser a sum of Rs_____(Rupees only) as Performance Security for the due and faithful performance of this Agreement, to be forfeited in the event of the Supplier failing duly and faithfully to perform it. Now these presents witness that for carrying duly and faithfully to perform it. Now these presents witness that for carrying out the said Agreement in this behalf into execution the Supplier and the Purchaser do hereby mutually covenant, declare, contract and agree each of them with the other of them in the manner following, that is to say,

1. The term "Agreement", wherever used in this connection, shall mean and include the terms and conditions contained in the invitation to Bid floated for the rate contract cum supply for Drug & Medicines For Rajasthan Medical Services Corporation, **(Two year Rate Contract ending on 30.09.2018) (F.02(191)/RMSC/PROCUREMENT/DRUG/NIB-10/2016/987 Dated: 26-07-2016)** and technical bid opened on **30.08.2016**, the instruction to Bidders, the conditions of Bid, acceptance of Bid, particulars hereinafter defined and those general and special conditions that may be added from time to time.

2. (a) The Agreement is for the supply by the Supplier to the Purchaser of the Drug and Medicines specified in the agreement on the terms and conditions set forth in the Agreement.

   (b) This Agreement shall be deemed to have come into force with effect from ***the date of issuance of letter of acceptance*** _____ and it shall remain in force upto **30.09.2018**.

   (c) The Bid quantity noted against each item in the schedule attached hereto indicates only the probable total requirements of the Purchaser in respect of each item for the Agreement Period indicated in Clause (b) above. This quantity may increase or decrease at the discretion of the Purchaser. The Supplier shall make supplies of the Drugs and Medicines on the basis of the Purchaser Orders placed on him from time to time by the ordering Authorities of the purchaser specifying the quantities required to be supplied required to be supplied at the specific location in the state of Rajasthan.

TERMINATION OF CONTRACT ON BREACH OF CONDITION

1 (a) In case the Supplier fails or neglects or refuse to faithfully perform any of the Covenants on his part herein contained, it shall be lawful for the Purchaser to forfeit the amount deposited by the Supplier as PERFORMANCE SECURITY and cancel the Contract.

(b) In case the Supplier fails, neglects, or refuse to observe, perform, fulfill and keep, all or any one or more or any part of any one of the Covenants, stipulation and provisions herein contained, it shall be lawful for the Purchaser on any such failure, neglect or refusal, to put an end to this Agreement and

thereupon every article, cause and thing herein contained on the part of the Purchaser shall cease and be void, and in case of any damage, loss, expenses, difference in cost or other moneys from out of any moneys for the time being payable to the Supplier under this and/or any other Contract and in case such last mentioned moneys are insufficient to cover all such damages, losses, expenses, difference in cost and other moneys as aforesaid, it shall be lawful for the Purchaser to appropriate the Performance Security made by the Supplier as herein before mentioned to reimburse all such damages, losses, expenses, difference in cost and other money as the Purchaser shall have sustained, incurred or been put to by reason of the Supplier having been guilty of any such failure, negligence or refusal as aforesaid or other breach in the performance of this Contract.

(c) If at any time during the course of the Contract, it is found that any information furnished by the Supplier to the Purchaser, either in his Bid or otherwise, is false, the Purchaser may put an end to the Contract/Agreement wholly or in part and thereupon the provisions of Clause (a) above shall apply.

2 The Purchaser reserves the right to terminate without assigning any reasons therefore the Contract/Agreement either wholly or in part without any notice to the Supplier. The Supplier will not be entitled for any compensation whatsoever in respect of such termination of the Contract/Agreement by the Purchaser.

NOTICE ETC, IN WRITING

3 All Certificates or Notice or orders for time or for extra, varied or altered supplies which are to be the subject of extra or varied charges whether so described in the Agreement or not, shall be in writing, and unless in writing, shall not be valid, biding or be of any effect whatsoever.

SUPPLIERS NOT HAVE ANY INTEREST IN THE OFFICERS CONCERNED AND SUBORDINATES

4 The Supplier shall not be in any way interested in or concerned directly or indirectly with, any of the Officers, Subordinate or Servants of the Purchaser. In any trade, business or transactions nor shall the Supplier give or pay or promise to give or pay any such Officer, Subordinate or Servant directly or indirectly any money or fee or other consideration under designation of

"Custom" or otherwise; nor shall the Supplier permit any person or persons whomsoever to interfere in the management or performance hereof under power of attorney or otherwise without the consent in writing the consent in writing of the Purchaser obtained in first hand.

BANKRUPTCY OF THE SUPPLIER

5 In case the Supplier at any time during the continuance of the Contract becomes bankrupt or insolvent or commits any act of bankruptcy or insolvency under the provisions of any law in that behalf for the time being in force, or should compound with his creditors, it shall be lawful for the Purchaser to put an end to the Agreement, and thereupon every article, clause and thing herein contained to be operative on the part of the Purchaser, shall cease and be void and the Purchaser shall have all the rights and remedies given to him under the preceding clauses.

SERVING OF NOTICE ON SUPPLIER

6 All notice or communication relating to or arising out of this Agreement or any of the terms thereof shall be considered duly served on or given to the Supplier if delivered to him or left at his premises, place of business or abode.

7 And it is hereby agreed and declared between the parties hereto that in case any question of dispute arises touching the construction or wording of any of clause herein contained on the rights, duties, liabilities of the parties hereto or any other way, touching or arising out of the presents, the decision of the Managing Director, Rajasthan Medical Services Corporation Ltd in the matter shall be final and binding.

8 All disputes arising out of this agreement and all questions relating to the interpretation of this agreement shall be decide by the Govt. and the decision of the Govt. shall be final.

SUPPLIER (Signature, Name & Address With Stamp)

EXECUTIVE DIRECTOR (P),
RAJASTHAN MEDICAL SERVICES CORPORATION LTD.

Witness (Signature, Name & Address)

1.

2.

Witness

1.

2.

-

ANNEXURE – V
Ref. Clause No. 5 (u)

Check List

Section	Details of requirement	Document Type	Yes/No If Yes Page No.
A	**BID SECURITY DEPOSIT, RISL Fess, Bid Processing Fees, Empanelment Fees.**	Challan/DD/ e–deposit generated receipt of Bid Security Deposit, bid fee and RISL fee and SSI certificate for exemption with Annexure-II	
B	**Technical documents**	Manufacturing License	
		Manufacturing License renewal /validity certificate	
		Non Conviction Certificate issued by the Drugs Controller	
		WHO-GMP Certificate	
		Import License, if imported.	
		Sale License, in the case of imported drugs	
		Copy of record of import to establish 3 years market standing, if imported.	
		Product Permissions by the Licensing Authority for each and every product quoted	
		Market Standing Certificate issued by the licensing Authority	
		Performance Statement	
		Annexure-VI Check List Of Details Regarding Products Quoted	
C	**Other Documents**	Documentary evidence for the constitution of the company / concern	
		The instruments such as power of attorney resolution of board etc	
		Copies of balance sheet & profit loss account for three years	
		Sales Tax clearance certificate	
		Excise Registration Certificate	
		Copy of PAN	
		Annual Turnover Statement	
		Annexure-VII Declaration and Undertaking	
		Annexure-XI Undertaking For Empanelment	

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Annexure – VI
Ref. Clause No. 5 (u)

Check list of details regarding products quoted

Product permission as per condition no. 5 (c) and Market Standing as per condition 5 (g)

S. No.	Quoted Item /Code no.	Product permission enclosed on page no.	Date of product permission / Approval	Product permission of formulation Generic / Branded	Specification as per Code no. Yes/ No	As per MSC product Mfg & Mkt since last 3 years			Performance Statement enclosed on page no.
						Page No.	Yes/ No	Date of Issue	
1									
2									
3									
4									
5									

-

Annexure – VII
Ref. Clause No. 5 (o),(q),(r),(t),(v),(w)

Declaration & Undertaking

(For F.02(191)/RMSC/PROCUREMENT/DRUG/NIB-10/2016/987 Dated 26.07.2016)

(On Non-Judicial Stamp Paper of Rs 500/-)

I Name……S/o…….Age……..Prop./Partner/Director/Power of attorney holder of firm M/s……situated at (Complete address of Mfg. unit)……bearing drug license on Form 25, 28, 10 etc bearing Number……. &……..respectively, issued on dated……..valid/Renewed up to……..do here by declare on oath as follows:-

1. That none of the quoted Drug and Medicines manufactured / imported by us since grant of above drug license have been found as of spurious or adulterated quality and no case in this regard is pending in any court.
2. That the quoted product is manufactured/imported by us, and none has been declared as "Not of standard quality" during last two years.
3. That we have following Commitment of quantity in our plant at above address:-[**Ref. Clause No. 24]**

S. No.	Quoted item Code No. & Name of Drugs	Monthly Capacity in all shifts in nos.	Annual Production Capacity	Monthly supply Commitment to RMSC in nos.	Supply Commitment quantity during rate contract period	Estimated Bid Quantity as per Annexure VIII
1.						
2.						

4. That concern/company/firm does not stand blacklisted/banned/debarred on any ground by Bid Inviting Authority or Govt. of Rajasthan or its departments on the date of bid submission.
   The concern/company/firm does not stand blacklisted/banned/debarred on the ground of conviction by court of law or the products being found spurious or adulterated by any other State /Central Government or it's any agencies (central Drugs procurement agencies). **But my firm is blacklisted/banned/debarred on a different ground by a**

procurement agency, the details of which are given below----------
----------(Write 'NIL' if no such matter exists)

5. That our Firm/Company and its Proprietor/Partner/Directors/ Power of attorney holders have not been convicted for contravention of any provisions of Drugs & Cosmetic Act 1940 and rules made there under since grant of license.
6. That we have been granted product permission by the State Licensing Authority for manufacture of quoted products as per the details given below:-

S. No.	Code No.	Name of the Product	Date of product permission obtained from the Licensing Authority	Whether Endorsement is in Generic or Trade Name	Issuing Licensing Authority	Own manufacturing / Loan Licensee (Please mention)	Drug manufacturing/Import License Number for quoted items
1.							
2.							

7. That we have over three years' experience in the manufacture of the quoted product, or the quoted imported product has over 3 years market standing.
8. That we have approved qualified staff, machines & equipments along with capacity to manufacture above category of drugs and our unit have been issued **WHO-GMP*** by Licensing Authority vide letter No…….dated…….valid upto……..
9. That we hereby confirm that we have deposited all the VAT/Sale Tax as on……..With the department No VAT/CST is due on M/s…….as on……..
10. That I will supply the Drug and Medicines per the designs given in Bid clause no 14 and as per the instructions given in this regard.
11. That I/We have carefully read all the conditions of Bid in Ref. no. F.02(191)/RMSC/PROCUREMENT/DRUG/NIB-10/2016/987 Dated: 26-07-2016 for Rate Contract cum Supply, of Drugs and Medicines (Two year Rate Contract ending on 30.09.2018) for Rajasthan Medical Services Corporation and accept all conditions of Bid, including amendments if

any. ***If case of typographical error found in submitted documents / affidavits, in this case we accept all the Terms and conditions of bid documents.***

12. I/We agree that the Bid Inviting Authority forfeiting the Bid security Deposit and or Performance Security and blacklisting /Debarring/Banning me/ us for a period of 5 years or as deemed fit if, any information furnished by us proved to be false/fabricated at the time of inspection and not complying the conditions as per Schedule M of the said Act or at any time during the Bid process.

13. I/ we hereby declare under Section 7 of Rajasthan Transparency in Public Procurement Act, 2012. that:
    b. I/we possess the necessary professional, technical, financial and managerial resources and competence required by the Bidding Document issued by the Procuring Entity;
    c. I/we have fulfilled my/our obligation to pay such of the taxes payable to the Union and the State Government or any local authority as specified in the Bidding Document;
    d. I/we are not insolvent, in receivership, bankrupt or being wound up. not have my/our affairs administered by a court or a judicial officer, not have my/our business activities suspended and not the subject of legal proceedings for any of the foregoing reasons;
    e. I/we do not have, and our directors and officers not have, been convicted of any criminal offence related to my/our professional conduct or the making of false statements or misrepresentations as to my/our qualifications to enter into a procurement contract within a period of three years preceding the commencement of this procurement process, or not have been otherwise disqualified pursuant to debarment proceedings;
    f. l/we do not have a conflict of interest as specified in the Act, Rules and the Bidding Document, which materially affects fair competition.

14. ***The quoted rates of any items is not more than the price fixed by the govt. under the current drugs (Price control) order.***

15. Our complete address for communication……
    ……
    ……

-

……Pin…….

E-mail address : - ……...

Phone No. /Mobile No……

16. Bank detail for e banking :-

Name of account holder ……..

Full name of Bank with Branch ……..

Address of Bank ……Pin……

A/c no. with full digits…….

IFSC code ……

17. Authorized/nominating person

Name: ……

Designation:-……

E-mail address:-…….

Phone No./Mobile No……

Photograph of Authorized/ nominating person

Signature of Authorized / nominating person

(Name of Deponent & Signature)
Designation

Verification

I……..S/o……(Designation)……Affirm on oath that the contents/information from para 1 to 17 as mentioned above, are true & correct to the best of my knowledge and nothing is hidden. I also declare on oath, that if any information furnished by me as above is found wrong, false, forged or fabricated; the Corporation will be at liberty to cancel the Bid for which I shall be solely responsible and the firm may be Debarred/Banned/ blacklisted / prosecuted for the same.

(Name of Deponent & Signature)

Witness :- (Name, Address & Signature)

1

2

*The WHO-GMP certificate must not be older than one year from the last date of Bid submission in case validity is not mentioned in the certificate.

-

Annexure – VIII
Ref. Clause No. 9 (2, 3)

List of Drugs with Specifications

S. No	Code No.	Name of item with specification	Packing Unit	Minimum labelled Shelf Life (In Months)	Estimated Bid Qty. for 2 year (No. of tabs, Caps, ampoules, bottles, tubes, tests etc.)	Remark
1	**2**	**3**	**4**	**5**	**6**	**7**
1.	5	Drotaverine Hydrochloride Injection 40 mg/2 ml	2 ml Amp (10 Amp)	36	2975904	
2.	6	Halothane BP 250 ml	250 ml in Amber coloured bottle	36	4900	
3.	9	Lignocaine Ointment 5%	10 gm tube in a unit carton	24	538078	
4.	51	Naloxone Injection IP 0.4mg/ ml	1 ml Amp (10 ampoules)	24	12412	
5.	54	Carbamazepine Tablets IP 100 mg (Film Coated)	10x10 Tab strip/Blister	36	4347000	
6.	60	Sodium Valproate IP Injection 100 mg/ ml	Vial	36	178854	
7.	81	Benzathine Benzylpenicillin Inj IP 12 lac units	Vial	24	92328	
8.	82	Benzathine Benzylpenicillin Inj IP 6 lac units	Vial	24	59252	
9.	110	Diethylcarbamazine Tablets IP 100 mg	10x10 Tab Blister	36	415402	
10.	117	Griseofulvin Tablet 125 mg	10 x 10 Tab Strip	36	3142560	
11.	136	Chlorambucil Tablets IP 5 mg	30 Tablets Bottle	24	32020	
12.	152	Mercaptopurine Tablets IP 50 mg	10 x 10 Tab strip	24	62600	
13.	158	Vinblastine Injection IP 10mg	Vial	24	4040	
14.	160	Levodopa and Carbidopa Tablets IP [Levodopa 100mg + Carbidopa 10 mg]	10 x10 Tab strip	36	270640	
15.	161	Levodopa 250mg and Carbidopa 25 mg Tab IP	10 x10 Tab strip	24	550200	
16.	180	Vitamin K Injection Each ml Contains Menadione Sodium Bisulphite 10mg Equivalent to 5.2 mg of Menadione. (Aqueous Solution)	1 ml Amp (Amber Colour) (25 Amp)	24	1016428	

S. No	Code No.	Name of item with specification	Packing Unit	Minimum labelled Shelf Life (In Months)	Estimated Bid Qty. for 2 year (No. of tabs, Caps, ampoules, bottles, tubes, tests etc.)	Remark
1	2	3	4	5	6	7
17.	211	Verapamil Tablets IP 40 mg (Film Coated)	10x10 Tab Strip	30	344720	
18.	225	Anti A Blood Grouping Serum IP (Anti A Monoclonal Serum)	10 ml Vial	12	119240	
19.	226	Anti B Blood Grouping Serum IP (Anti B Monoclonal Serum)	10 ml Vial	12	122064	
20.	227	Anti DRH Blood Grouping Serum IP	10 ml Vial	12	132292	
21.	232	Diatrizoate Meglumine and Diatrizoate Sodium Inj USP 60% (iodine conc = 292 mg/ml)	20 ml Amp	36	3000	
22.	244	Compound Benzoin Tincture IP	500 ml Bottle	30	295956	
23.	252	Surgical Spirit IP/BP	500 ml Opaque white colour bottle with Inner Cap	36	684702	
24.	278	Sodium Phosphates Enema BP Each 100ml contains Sodium Dihydrogen phosphate Dihydrate 10%, Disodium Hydrogen Phosphate Dodecahydrate 8%	100 ml polypropylene pack	24	1467442	
25.	282	Clomifene Tablets IP 25 mg	10 x10 Tab strip	24	88480	
26.	284	Conjugated Estrogen Tabs USP 0.625 mg.	10x10 Tab or 1x28 Tab Strip/Blister(Rate should be quoted for one Tablet)	36	121770	
27.	285	Dinoprostone Cream/Gel 0.5 mg Dinoprostone in syringe	Pre - Filled Syringe	24	224906	
28.	286	Ethinyloestradiol Tabs IP 50 mcg	10x10 Tab Strip	24	132660	
29.	305	Human Rabies Immunoglobulin Injection 150 IU/ ml	2 ml vial/Ampoule/PFS	24	32284	

S. No	Code No.	Name of item with specification	Packing Unit	Minimum labelled Shelf Life (In Months)	Estimated Bid Qty. for 2 year (No. of tabs, Caps, ampoules, bottles, tubes, tests etc.)	Remark
1	2	3	4	5	6	7
30.	310	Tetanus Vaccine (adsorbed) I.P.	5 ml Vial	36	1641526	
31.	314	Neostigmine Injection IP 0.5 mg/ml	1ml Amp (10 ampoules)	24	251774	
32.	316	Neostigmine Tablets IP 15 mg	10x10 Tab Strip	24	48616	
33.	320	Atropine Sulphate Ophthalmic Solution USP 1%	5ml vial with sterilized dropper, or squeeze vial	24	52770	
34.	326	Pilocarpine Eye Drops IP 2%	5ml squeeze vial	24	25612	
35.	338	Oxytocin Injection IP 5 IU/ml	1 ml Amp (Single Unit in Blister pack)	24	9275940	
36.	342	Chlordiazepoxide Tablets IP 10mg	10 x10 Tab Strip	24	4647160	
37.	343	Chlorpromazine Tablets IP 100 mg (Coated Tablet)	10x10 Tab strip	24	1866860	
38.	344	Chlorpromazine Tablets IP 25 mg (Sugar- Coated)	10 x10 Tab Strip	36	907522	
39.	345	Chlorpromazine Tabs IP 50 mg. (Coated Tablets)	10x10 Tab Strip	36	2935306	
40.	346	Chlorpromazine Inj. IP 25mg/ml	2 ml Amp (25 ampoules)	24	22644	
41.	359	Lorazepam Injection 2 mg/ml	2 ml Amp (25 ampoules)	24	236534	
42.	376	Theophylline Tablets 400 mg Sustained release/controlled release (Theophylline prolonged Release Tablets IP)	10x10 Tab Blister	24	6721734	
43.	383	Potassium Chloride Injection 0.15 gm/ml	10 ml Amp (10 ampoules)	24	564716	
44.	384	Potassium chloride Oral Solution U.S.P 500mg/ 5ml	200 ml Bottle (Amber colour) with Measuring Cap	36	57222	
45.	388	Calcium Gluconate Injection IP 10% (IV use)	10 ml Amp (25 ampoules)	36	1227764	
46.	397	Vitamin – B complex tablet NFI(prophylactic) B1- 2mg, B2- 2mg, B6-0.5mg, Niacinamide 25mg, Calcium pantothenate 1mg (With appropriate overages)	10 x 10 Tab Strip/ blister	24	221894552	

S. No	Code No.	Name of item with specification	Packing Unit	Minimum labelled Shelf Life (In Months)	Estimated Bid Qty. for 2 year (No. of tabs, Caps, ampoules, bottles, tubes, tests etc.)	Remark
1	2	3	4	5	6	7
47.	398	Black Disinfectant Fluid (Phenyl) (As per Schedule "O" Grade – III	5 Lit Can	18	423404	
48.	399	Concentrated Solution for Haemodialysis B.P Acetate concentrate in 10 Litre Cans.	10 Ltrs Plastic Can	24	24600	
49.	420	Phenobarbitone Injection IP 200mg/ml	1 ml ampoule/vial	24	232168	
50.	424	Lidocaine Hydrochloride Topical Solution USP 4%	30 ml Vial	36	21456	
51.	425	Fluconazole Eye Drops 0.3%	5 ml vial with sterilised dropper, or, squeeze vial.	24	81900	
52.	444	Aspirin Delayed Release Tablets / Aspirin Gastroresistant Tablets. Each enteric coated tablet contains Acetyl Salicylic Acid 75 mg	10 x 14 Tablets Strip	24	26992758	
53.	449	Surgical Spirit IP/BP	100 ml Opaque white colour bottle with Inner Cap	24	1902266	
54.	457	Amlodipine and Enalapril Maleate Tablet (Amlodipine Besilate equivalent to Amlodipine 5mg, Enalapril maleate 5mg)	10 x 10 Tab Strip	24	1806500	
55.	474	Carbamazepine Oral Suspension USP 100 mg/5ml	100 ml Bottle with measuring Cap	24	39490	
56.	536	Methotrexate Tablets IP 10 mg	10x10 Tablet Strip	24	328660	
57.	559	Betamethasone Lotion IP 0.05%	50 ml	24	486000	
58.	577	Terazosin Tablets USP 1 mg	10x10 Tablet	24	8000	
59.	592	Lactic Acid Bacillus Tablets 60 million spores	10x10 Tablet	24	48649850	
60.	604	Glucagon for Injection USP 1 mg	Vial	24	2284	
61.	605	Medroxyprogesterone acetate Tablets IP 10 mg	10x10 Tablet	24	437620	

S. No	Code No.	Name of item with specification	Packing Unit	Minimum labelled Shelf Life (In Months)	Estimated Bid Qty. for 2 year (No. of tabs, Caps, ampoules, bottles, tubes, tests etc.)	Remark
1	**2**	**3**	**4**	**5**	**6**	**7**
62.	612	Betaxolol Eye Drops 0.5%	5 ml Squeeze Vial	24	5700	
63.	614	Phenylephrine Hydrochloride Ophthalmic Solution USP/ Phenylephrine Eye Drops BP 5%	5 ml Squeeze vial	24	43892	
64.	619	Terbutaline Tablets IP 2.5 mg	10x10 Tablet	24	621760	
65.	215A	Cetrimide Cream IP	15 gm Tube in unit carton	24	1771830	
66.	NE2	Misoprostol Tablets IP 200 mcg	30x3 Tablets (Pack of 3 Tablets and user guide line in a unit Carton) **(Rate should be quoted for 90 tablets)**	24	210000	User Guide line As per Annexure 'A'
67.	NE3	Treponemal-Specific Rapid (Point-of- Care) Diagnostic Test for Syphilis	50 Tests per kit **(Rate should be quoted for one kit which contains 50 tests)**	As per Annexure 'B'	450000	Specification As per Annexure 'B' and Sample required as mentioned at point no 15 of General Requirement.
68.	490 W	IRON AND FOLIC ACID TABLETS (WIFS JUNIOR) Each Sugar coated tablet contains: Dried Ferrous Sulphate IP equivalent to Ferrous iron 45 mg Folic Acid IP 0.4 mg The tablets are Pink coloured.	10 X 15 Tablets Strip	24 (Remaining Shelf life at the time of delivery - 5/6th of labeled Shelf life)	166350500	Other Additional Specific requirement given in Bid condition '15(A)'
69.	489P	IRON AND FOLIC ACID TABLETS (IFA WIFS) Each enteric coated tablet contains:	10 X 15 Tablets Strip	24 (Remaining Shelf life at the time	193320000	Other Additional Specific requirement given in Bid

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S. No	Code No.	Name of item with specification	Packing Unit	Minimum labelled Shelf Life (In Months)	Estimated Bid Qty. for 2 year (No. of tabs, Caps, ampoules, bottles, tubes, tests etc.)	Remark
1	**2**	**3**	**4**	**5**	**6**	**7**
		Dried Ferrous Sulphate IP equivalent to Ferrous iron 100 mg Folic Acid IP 0.5 mg The tablets are Blue coloured (Indigo Carmine)		of delivery - 5/6th of labeled Shelf life)		condition '15(B)'
70.	448 W	IRON AND FOLIC ACID SYRUP IP Each ml of Syrup contains Ferrous Sulphate IP Equivalent to elemental ferrous iron 20 mg, Folic Acid IP 0.1 mg	50 ml Bottle (Amber Colour) with Auto dispenser to dispense 1 ml each time, Packed in a unit carton	18 (Remaining Shelf life at the time of delivery - 3/4th of labeled Shelf life)	17152400	Other Additional Specific requirement given in Bid condition '15(C) and 15(C)(C)'

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Note:-

The above quantity mentioned for this supply cum rate contract is indicative and may vary as per the actual requirement of hospitals.

The bidder should quote rate for the above mentioned packing unit only.

General Requirement:-

1. The manufacturer should ensure Stability of the formulations and its ingredients in the packing supplied.
2. The blister packing of tablets/Capsules should have Aluminium foil back.
3. Strip packing should be of Aluminium / Alu- Alu foils.
4. Aluminium foil strips refer to thickness not less than 40 microns.
5. The rigid PVC used in blister packing should be of not less than 250 microns.
6. Small tablets packed in blister should be packed to facilitate easy removal of a tablet without breaking/ crushing.
7. Containers for 400 ml (or 400 gm) or more, should have an inner lid also.
8. ***Syrup and Suspension should be palatable enough.***
9. ***The measuring cap / dropper supplied with oral liquid formulation should have suitable marking.***
10. ***The minimum size (length x breadth) of a blister strip shall be 6.5cm X 3cm.***
11. ***Generic name of a drug should be printed in clearly legible bold letters. The font size of the name of drug on any tablet strip/ blister shall not be less than '9' in bold capital letters of Times New Roman or Arial font, e.g.,*** LOSARTAN TABLETS IP ***even on small strips/ blisters. The font size shall be correspondingly bigger on bigger strips / blisters. Besides this, other contents on the label should also be legible.***
12. ***The stereo printing of batch no. , Mfg date, Exp date on the reverse side of strip/blister should run atleast two times.***
13. ***The secondary packing (unit carton) should contain 10x10 or 20x10 capsules for item code 639, 640 and 641.***
14. **Quote rate in BOQ for the packing exactly given in annexure VIII. For example**
    - **If the packing unit is given for 10x10 tablets / capsule, the rate should be quoted for 10x10 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.**
    - **If the packing unit is given for 10x10x1 tablets / capsule, the rate**

should be quoted for 10x10 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.

- **If the packing unit is given for 10x14 tablets / capsule, the rate should be quoted for 10x14 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.**
- **If the packing unit is given for 2 ml ampoule (25 ampoules), the rate should be for 25 ampoules and not for 1 ampoule or 10 ampoules etc.**
- **If the packing unit is given for 2 ml ampoule (10 ampoules), the rate should be for 10 ampoules and not for 1 ampoule etc.**

15. PRODUCTION OF SAMPLES

1 Bidder shall submit one kit (50 Test) for ***item code NE3 - Treponemal-Specific Rapid (Point-of- Care) Diagnostic Test for Syphilis***, free of cost. The items submitted as samples should be of the same specifications as asked for in the bid. Any deviation from specifications will result in the rejection of the sample. The samples (normal/ regular sales packs) will be used for quality evaluation by the technical evaluation committee and/ or laboratory analysis, as the case may be, as decided by the Tender inviting authority. Samples of the items which are supposed to be sterile should be sterile. The decision based on quality evaluation of the sample will be final for the purpose of this tender.

2 The samples for evaluation shall be submitted in a separate sealed cover superscripted by "Tender No. _____". The sample as above shall be submitted at the time of depositing Bid Security, or within 10 days of technical bid opening. The bidder should submit, along with the samples, the list of sample items in the given format in Annexure -XVI.

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Annexure 'A'

USER GUIDE LINE FOR MISOPROSTOL TABLETS IP 200 mcg

मीज़ोप्रोस्टॉल गोलियों के वितरण और सलाह-मश्वरा के लिए जॉब-एड

क्या देना है	3 गोलियों का एक पैकेट 
कितनी बार	केवल एक बार (3 गोलियाँ) 
किसे देना है	गर्भवती महिला को आठवें महीने में 
कब लेना है	• प्रसव के दौरान शिशु जन्म के बाद • सुनिश्चित करें कि गर्भ में दूसरा बच्चा नहीं है • बच्चा होने के तुरन्त बाद और प्लैसेन्टा/फूल निकलने से पहले • प्लैसेन्टा/फूल निकलने के तुरन्त बाद भी ले सकते हैं 
कब नहीं लेना है	• बच्चा होने से पहले • ऐसे समय लेने से माँ और बच्चे को मृत्यु का ख़तरा हो सकता है 
कहाँ लेना है	• घर पर प्रसव होने पर शिशु जन्म के तुरन्त बाद • यदि प्रसव और शिशु जन्म रास्ते में हो जाएँ 
कहाँ रखें	सुरक्षित सूखे स्थान पर नमी, गर्मी और बच्चों से दूर 
कैसे लेना है	पानी के साथ तीनों गोलियाँ खानी हैं 

मीजोप्रोस्टॉल गोलियों के सामान्य दुष्प्रभाव

सामान्यत: ये प्रभाव हानिकारक नहीं होते और अपने आप कुछ घंटों में समाप्त हो जाते हैं

- बुखार/सिहरन
- मितली/उल्टी
- पेट के ऊपरी हिस्से में दर्द
- दस्त/कब्ज़
- सिरदर्द
- तीव्र एलर्जी प्रभाव (बहुत कम)



सावधानियाँ

निम्न अवस्थाओं वाली गर्भवती महिलाओं को प्रसूति के लिए स्वास्थ्य केन्द्र पर रेफर करना ज़रूरी है

- जुड़वाँ बच्चे हों
- पहले, ऑपरेशन से बच्चा हुआ हो
- बच्चेदानी का कोई ऑपरेशन हुआ हो
- उल्टा (ब्रीच) या आड़ा बच्चा पहले या इस गर्भावस्था में हो
- खून की कमी (एनीमिया) हो
- दिल की बीमारी हो
- उच्च रक्तचाप या दौरे हों
- अन्य चिकित्सीय जटिलता हो

USAID ACHIP

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Annexure 'B'

Technical Specifications of Treponemal-specific Rapid (Point-of-Care) Diagnostic Test for Syphilis

1. The assay may be based on any of the rapid test principles: (immunoconcentration/ immunofiltration/immunochromatography).
2. The assay should quantitatively detect total anti-treponemal antibody (IgG and IgM) in whole blood, serum or plasma for serological diagnosis of syphilis in all stages of infection.
3. The assay should have an in-built procedural control in form of bend or dot for validation of the test kits.
4. The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size).
5. The kit should have $5/6^{th}$ of the shelf life or 12 months before expiry (whichever is more) at the time of receipt by the consignee.
6. Adequate literature detailing the principle, components, methodologies, validity criteria, bio-safety, performance characteristics, storage conditions, limitation of assay, manufacture and expiry dates and methods of disposal should be provided with each kit.
7. The imported rapid kit should have approval of the statutory authority in its country of origin. The imported kits should have been registered and licensed in India by the Central Drugs Standard Control Organization (CDSCO).
8. In case of indigenous manufacturers they should have a valid license issued by the competent authority defined under Drugs and Cosmetics Act, 1940, after appropriate evaluation by the centres approved by the CDSCO.
9. The assay should have sensitivity of 90% or more and specificity of 95% or more and the same should be supported by statements in kit insert and certificate from National Institute of Biological Sciences.
10. The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit insert and certificate from the manufacturer.
11. Test procedure should be user friendly (can be performed with few simple steps with minimum training)
12. The manufacturer should ensure the following:
    - Test should be equipment free. Result should be visualised with nacked eye.
    - The test should be packed such that there is a provision to conduct single test at a time.
    - The pack size of test lots should be in 50 (for peripheral health levels) and 100 tests per kit (for secondary and tertiary health care level) but not more than 100 tests per kit.
13. The manufacturer should ensure maintenance of cold chain during storage and transport of kits at 2°C to 8°C in form of transtracker on every kit.
14. Total procedure time should not be more than 30 minutes.
15. Quantity 9000 Pkt (50 Units per Packet)

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Annexure -IX
Ref. Clause No. 13, 16 & 19

RAJASTHAN MEDICAL SERVIC,ES CORPORATION

GUIDELINES FOR BLACKLISTING/DEBARRING OF PRODUCT OR SUPPLIER/COMPANY

1. ON SUBMISSION OF FALSE, FORGED OR FABRICATED DOCUMENTS OR CONCEALING OF FACTS:

The Bidder who submits false, forged or fabricated documents or conceals facts with intent to win over the Bid or procure purchase order; Bid Security Deposit of such Bidder firm will be forfeited and firm will be liable for blacklisting for a period of not Less than 2 years. The firm will also be liable for Legal action depending on the facts & circumstances of the case.

2. ON ACCOUNT OF FAILURE TO ENTER INTO AGREEMENT OR WITHDRAWL AFTER AGREEMENT OR REFUSAL / FAILURE TO SUPPLY:

2.1 The successful Bidder fails to execute the agreement after being declared as L-1, L-2 or L-3 etc. to perform the obligations under the Bid conditions, Bid Security Deposit of such Bidder firm will be forfeited and firm will be liable for blacklisting for a period of not less than 2 years or the period specified in Bid document.

2.2 The successful Bidder after entering into an agreement withdraw or fail to honour commitments as per Bid conditions, Performance Security of such Bidder firm will be forfeited and firm will be liable for blacklisting for a period of not Less than 2 years.

3. ON ACCOUNT OF NON-SUPPLY:

3.1 The supplier shall start to supply according to Bid condition from the date of purchase order and shall complete the supplies within 45/60 days as mentioned in Purchase Order or as stated in Bid condition.

3.2 RMSC will be at liberty to accept or reject the supply made belatedly as per the terms and conditions of the Bid documents. In the event of

acceptance of delayed supply the liquidated damages shall be imposed at the rate stipulated in conditions of the Bid document.

3.3 If the supplier fails to execute the purchase order and informs RMSC about its inability to execute the order and non-compliance of the purchase order due to act of vis-majeure, then the Managing Director, RMSC will issue appropriate order on merits of case.

3.4 If the supplier fails to execute atleast 50% of the quantity mentioned in single purchase order and such failure in supply continues for three purchase orders, then supplier firm will be liable for blacklisting for a period of not Less than 2 years. As a result such supplier will be ineligible to participate in any of the Bids for particular item(s) of drugs / medicines for a period of not less than 2 years or the period specified in Bid document.

4. ON ACCOUNT OF QUALITY FAILURE OF DRUGS & MEDICINES:

4.1. The drugs supplied by the suppliers to the District Drug Warehouses are quarantined and samples of each and every batch of drugs /medicines are drawn on random basis and forwarded to Quality Control Wing of RMSC at the headquarter. The samples are then sorted; common batches pooled, coded and are sent to the empanelled laboratories for quality control test as per the QC Policy of RMSC.

4.2. Samples of all sterile surgicals & sutures items falling in the categories of drugs will also be drawn as per above policy and all of them will be subjected essentially for sterility testing.

4.3. If such samples pass quality test in all respects, RMSC will instruct its Warehouses to issue items of drugs to various hospitals / institutions

4.4. If the sample fails in quality test and report is received certifying that sample is not of standard quality, the drugs of the batch will not qualified for issue and supplier shall be informed to take back stocks of such batch, which failed the quality test and other consequences would follow as per the conditions in the Bid documents.

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4.5. ***Minor Defects***

(1) If any batch of a particular item supplied under a tender tenure by the supplier is declared as Not of Standard Quality during its entire shelf life by an empanelled lab or Govt. Lab in test for assay and dissolution*/ or in any other parameter(s) and if such failure is further confirmed by another empanelled lab or Govt. Lab during its entire shelf life, the particular drug shall be liable for debarring for a period of not Less than one year.

(2) If two or more batches of a supplier of a single drug or multiple drugs supplied under a tender tenure by the supplier is declared as Not of Standard Quality for minor defects, and such failure are further confirmed by another empanelled lab / Govt. Lab, then the product(s) of these batches shall be liable for debarring for a period of not less than two years.

(*Tablets/Capsules failing in dissolution test and active contents found 70% and above for thermo labile products, and upto 5% less than the prescribed limits for thermo stable products.)

4.6. ***Grossly Substandard***

(1) ***If any batch of a particular item supplied under a tender tenure by the supplier is declared as Not of Standard Quality by an empanelled lab or Govt. Lab which falls in grossly substandard category and such failure is further confirmed by another empanelled lab / Govt. Lab, then the product shall be liable for debarring for a period of not Less than one (1) years.***

(2) ***If two or more batches supplied under a tender tenure by the supplier is declared as Not of Standard Quality by an empanelled lab or Govt. Lab, which falls in grossly substandard and such failure is further confirmed by Govt. Lab, then the Company shall be liable for debarring for a period of not less than two (2) years.***

4.7. In case three products of a company/supplier are blacklisted for supply made during a Bid duration the Supplier / Company shall be liable for blacklisting for a period of not Less than 2 years.

4.8. ***Spurious or Adulterated***

In case, any sample (even one batch) is declared as Not of Standard Quality by an empanelled lab or Govt. Lab which falls in Spurious or Adulterated category and if such failure is further confirmed by Govt. Lab during its entire shelf life, the Company shall be liable for debarring for a period of not less than 3 years.

if a company is debarred because of supply of Grossly Sub Standard and/or spurious/adulterated drugs, rate contracts with the delinquent company for other drugs will continue to be in force so far as these other drugs are found to be of 'Standard Quality'.

4.9. If any statutory sample of RMSC supply drug is drawn by Drugs Control Officer on suo-moto basis or on complaint and if it fails in quality parameters, the report is conclusive till it is challenged by supplier / company. If it is challenged then the report of Director, C.D.L., Kolkatta shall be conclusive and action as contemplated in foregoing paragraphs will be initiated in the matter of blacklisting of product or company. However if failure is of such nature wherein Drugs Controller of State grants prosecution sanction under Drugs & Cosmetics Act, 1940, then even failure of such one batch shall be considered adequate for blacklisting the product for not less than 2 years and in case of involvement of three different products the **Supplier / Company** as a whole shall be liable for blacklisting for a period of not Less than 3years.

5. PROCEDURE IN THE EVENT OF QUALITY FAILURE WILL INVOLVE THE FOLLOWING STEPS:

5.1 On receipt of adverse quality test report from empanelled lab or Govt. Lab of a quarantined stock, instructions will be issued immediately through e-mail to the concerned District Drug Warehouses to not to release such stock and entries be made by QC Cell at headquarter in e-aushadhi software for batch rejection i.e. not to be released for distribution to institutions / DDC's.

5.2 Warehouse Incharge will take appropriate measures immediately to segregate such stock and label all cartons as "NOSQ Drugs-Not for release" and shift it from quarantine area to Non-Release / Rejected Drugs Area (which is under lock & key) till its lifting by the supplier.

5.3 Immediately on receipt of NOSQ report, the second sample should be sent to another empanelled lab / Govt. Lab by the QC Cell.

5.4 The supplier shall be informed immediately about the test results and instructions be issued to lift the entire stock at supplier's expenses of

such batch no. drug which is declared as "NOSQ" by the empanelled lab / Govt. Lab. However, in case of serious quality failure i.e. if drug is declared or adjudged spurious, adulterated or grossly substandard, one of drug warehouse incharge will be directed to contact the District Drugs Control officer for drawing statutory sample of such batch as per Act. The DDW Incharge has to keep adequate quantity of such drug for statutory sampling by Drugs Control officer.

5.5 In case of drug declared as **Not of Standard Quality** on subsequent sampling after the batch was released the procedure given in sub-para 5.2 will be followed in respect of stock available with the warehouse. In respect of stock already issued and drug warehouse in charge will take immediate steps to RETRIEVE the unused stock of such drugs from all such institutions and D.D.C.s by all possible mode and means and he/she will ensure that no such NOSQ drug is further distributed to the patients and ensure effective recall.

5.6 On receipt of test report from empanelled lab / Govt. Lab, show cause notice will be issued immediately to the concerned supplier calling for explanation within 3 days from the date of receipt of notice in respect of quality failure of concerned batches of drug. The supplier will be required to submit the batch manufacturing record, batch analysis report, raw material purchase record & raw material test reports etc. Opportunity for personal hearing, if desired by supplier, may also be accorded.

5.7 On confirmation of the test result by the second laboratory, the case will be referred to the disciplinary committee of RMSC for further action.

5.8 In case when the second report is contradictory to the first report, the statutory sample will be sent to Govt. Lab, whose report will be final and if the sample has been tested by the Govt. Lab at any stage, its report will be conclusive & final unless challenged as per provisions of Drugs & Cosmetics Act, 1940.

6. EXAMINATIONS OF ISSUES BY DISCIPLINARY COMMITTEE OF RMSC

6.1. Each & every case of submission of false documents, failure to execute agreement, non-supply or quality failure, etc. will be referred to disciplinary committee of RMSC for examination on a case to case basis for making appropriate technical recommendation to Managing Director for further appropriate action.

6.2. The recommendations of disciplinary committee will be placed before the Managing Director, RMSC who shall take appropriate action which may deem fit in the light of facts & circumstances of the case by way imposing penalty or debarring or Blacklisting of the particular product or supplier/ company.

6.3. If, the quality failure is of such nature that a particular product has been blacklisted according to the procedure stated above, the supplier will not be eligible for participating in any of the Bids for the particular item floated by RMSC for the specified period. For such purpose period of blacklisting will be counted from date of issue of order and it will deemed to be over on completion of the period and as such no fresh orders will normally be required for re-eligibility purpose. Similarly if the supplier /company is blacklisted the supplier will not be eligible for participating in any of the Bids for any of the items during blacklisted period.

7. POWER OF REVIEW:

Subsequent to the action taken on the basis of available facts if some new facts & evidences such as reversal of test results findings by Appellate Laboratories etc. are brought to the notice of the corporation, the Managing Director of RMSC will have the right to review the earlier action. He may seek advice from the disciplinary committee in such matters.

8. RIGHT TO APPEAL:

Any supplier / company against whom the above action is taken may prefer an appeal within 30 days of date of blacklisting order to the Principal Health Secretary, Medical & Health Department, Govt. of Rajasthan who shall decide the same.

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9. Savings:

The blacklisting of particular product or supplier / firm will be done without prejudice to other penalty which may be imposed as per the conditions of Bid documents and also to other actions which may be initiated under Drugs and Cosmetics Act 1940 or any other law of land. RMSC will display names of such blacklisted products and companies on its website and also circulate the same among all stakeholders viz. PSME, DM&HS, DC including respective State Drug Controllers where the supplier / company is located.

10. JURISDICTION:

In the event of any dispute arising out of the orders and implementation thereof, such dispute shall be subject to the jurisdiction of the Courts of Jaipur City only or Hon'ble Rajasthan High Court, Bench at Jaipur.

EXPLANATIONS:

(i) Increase in the cost of raw materials, power cut, Labour strike, insolvency, closure of the factory would not be considered as act of vis-majeure.

(ii) ***For the drugs failing in Quantative analysis (Assay), following treatment is to be given:-***

On the basis of quantitative analysis (Assay), the NOSQ drug shall be distinguished in the following manner :-

Category of NOSQ drugs	***Active ingredient content (Assay)***	
	Thermo stable	***Thermolabile***
Minor	***Upto 5% less than the prescribed lower limit***	***Above 70% to the prescribed lower limit***
Grossly Substandard	***Below 5% of the prescribed lower limit to 50%***	***70% to 40%***
Spurious	***Below 50%***	***Below 40%***

(iii) Purchase Orders, if any, already issued before taking any blacklisting action or replacement orders given in past will not be affected in view of action taken as per above guidelines

(iv) The action proposed as above is not in conflict to any express conditions laid down in corresponding Bid and in case of any overlapping, the Bid condition will prevail.

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ANNEXURE-X
FORM NO. 1 [See rule 83 of RTPP]

Memorandum of Appeal under the Rajasthan Transparency in Public Procurement Act, 2012

Appeal No..... of.....
Before the..... (First/Second Appellate Authority)

1. Particulars of appellant:
   (i) Name of the appellant:
   (ii) Official Address, if any:
   (iii) Residential address:

2. Name and address of the respondent (S):
   (i)
   (ii)
   (iii)

3. Number and date of the order appealed against and name and designation of the officer/ authority who passed the order (enclose copy), or a statement of a decision, action or omission of the Procuring Entity in contravention to the provisions of the Act by which the appellant is aggrieved:

4. If the Appellant proposes to be represented by a representative, the name and postal address of the representative:

5. Number of affidavits and documents enclosed with the appeal:

6. Ground of appeal:
.....
.....
..... (Supported by an affidavit)

7.
Prayer:
.....
.....
Place.....
Date.....

Appellant's Signature

-

ANNEXURE-XI
Ref. Clause No. 1(d), 5(y), 20

UNDERTAKING FOR EMPANELMENT

I Name…….S/o…….Age……..Prop./Partner/Director/ Power of attorney holder of firm M/s……..situated at (Complete address of Mfg. unit)…….bearing drug license on Form 25 & 28 or form 10 bearing Number……. &……..respectively, issued on dated……..valid/Renewed up to……..do here by declare on oath as follows:-

1. That I have applied for empanelment for supply of Drugs & Medicines for the items I have quoted in the bid as enlisted in Annexure –VII
2. That I/We have carefully read all the conditions of Bid in Ref. no. F.02(191)/RMSC/PROCUREMENT/DRUG/NIB-10/2016/987 Dated: 26-07-2016 for supply Cum rate contract and empanelment for supply of Drug and Medicines For Rajasthan Medical Services Corporation and accept all conditions of Bid, including amendments if any.
3. That I will be considered empanelled for the items which are declared technically responsive.
4. That I have deposited the required fees for empanelment or previous bid ref no……

Date

Name & Signature with Seal

-

Annexure-XII
Ref. Clause No.17.2

Supplier Consolidated Invoice

Name of Supplier: …….
Complete Address: ……..
E-mail ID: ……..

DL NO.:	TIN No.:	Invoice No.: Date:

Purchaser: Managing Director **Address:** Rajasthan Medical Services Corporation, Gandhi-Block, Swasthaya Bhawan, Tilak Marg, C-Scheme, Jaipur Phone No. 0141- 2228066 RMSC TIN NO.08404750762	Purchase Order No.: …….. Date: ……..

Name of Item/Description : …….. **Drug Code (RMSC) : ……**

S.No	Name of DDW	Odered Qty.	Invoice/ Challan no.	Date	Packing Size	Batch No.	Mfg. Date	Exp. Date	Quantity Supplied in No. (Batch wise)	Basic Rate (without Concessional CST)	Basic Amount (without Concessional CST)
1	2	3	4	5	6	7	8	9	10	11	12

Remarks:	Total Basic Amount	
	Rate of (%) Concessional CST against C-form & Total Tax Amount	
	TOTAL INVOICE AMOUNT	

Authorised Signatory

-

Annexure-XIII
Ref. Clause No. 17.2

Analytical Report Regarding Quality

Name of Supplier:-						
Address:-						
PO No:-		**Date:-**				
Drug Name:-						
Details of in house test report:-						
S. No.	**Name of Lab.**	**Test report No.**	**Date**	**Batch No.**	**Qty. Supplied**	**Result**
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						

Authorised Signatory

-

Annexure-XIV
Ref. Clause No. 11

Security form (Bank guarantee)

To,

Managing Director Rajasthan Medical Services Corporation Ltd
WHEREAS…….(Name of Supplier)

Hereinafter called "the Supplier" has undertaken, in pursuance of Contract (Letter of Acceptance) No……dated……2016 to supply……(Description of Goods) hereinafter called "the Contract".

AND WHEREAS it has been stipulated by you in the said Contract that the Supplier shall furnish you a bank Guarantee from a Scheduled Bank for the sum specified therein as security for compliance with the Supplier's performance obligations in accordance with the Contract.

AND WHEREAS we have agreed to give the supplier a Guarantee:

THEREFORE WE hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, up to a total of ……..(Amount of the Guarantee in Words and Figures) and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the said Contract and/or any other contract or for set off any other dues pending against the supplier, without cavil or argument, any sum or sums within the limit of ……(Amount of Guarantee) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This Bank guarantee is payable at Jaipur Branch ……

This guarantee is valid until the……day of……2019……...

Signatures and Seal of Guarantors

Date……

Address:……
……

Note:- The validity of bank guarantee should be for 36 months from the date of issuance of Bank Guarantee.

-

Annexure-XV
Ref. Clause No. 2 (c)

PERFORMANCE STATEMENT

(*The statement may be given for year 2012-13, 2013-14, 2014-15 or 2013-14, 2014-15, 2015-16*)

Name of Firm : ……

S. No.	Item Code no.	Name of Item	Financial Year		Financial Year		Financial Year	
			No. of Batches manufactured	No. of Batches declared NOSQ	No. of Batches manufactured	No. of Batches declared NOSQ	No. of Batches manufactured	No. of Batches declared NOSQ

The information as given above is true and correct. If any information furnished by me as above is found wrong; I shall be solely responsible and suitable action may be taken against my firm.

Signature & Seal of the Bidder

-

ANNEXURE-XVI
Ref Clause -General Instruction point no 15(2)

PROFORMA FOR SUBMISSION OF SAMPLES *FOR ITEM CODE NE3*

(Treponemal-Specific Rapid (Point-Of- Care) Diagnostic Test For Syphilis)

Tender No. _____

Name of Bidder _____

Address _____

_____

_____

S.No	Item Code	Name of the Item	Commercial Sample Submitted	
			Qty	Batch No.
1	*NE3*	***Treponemal-Specific Rapid (Point-of-Care) Diagnostic Test for Syphilis***		

Signature & Seal of the Bidder

Date :