Ref. No.: F.02(283)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-08/2020/990 Dated :11.06.2020

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,
edprocurement@gmail.com

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS (Ending on 31.03.2022)

!! सर्वे सन्तु निरामयाः!!

LAST DATE OF SUBMISSION OF ONLINE BIDS	**13-07-2020 & 6.00 PM**
DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS	**14-07-2020 & 11.00 AM**

Ministry of Health & Family Welfare
Government of Rajasthan
RMSCL
"Mukhyamantri Nishulak DavaYojana"
'D' Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India
Tel No: 0141-2228066, 2228064, E-mail: rmsc@nic.in

Ref. No.: F.02(283)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-08/2020/990 Dated :1106.2020

Notice Inviting E-Bids

E-bids are invited up to 6.00 PM of 13-07-2020 from approved Drugs Testing Laboratories situated in India for analysis of Drugs. (Ending on **31.03.2022**) Details 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

(UBN :-MSC2021SLRC00016)

Executive Director (Procurement)
RMSCL

RAJASTHAN MEDICAL SERVICES CORPORATION LTD. RAJASTHAN

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS (Ending on 31.03.2022)

Bid Reference	**:**	F.02(283)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-08/2020/990 Dated :1106.2020
Pre- bid conference	**:**	**16-06-2020 at 11.00 A.M.** (RMSC meeting Hall)
Date and time for downloading bid document	**:**	**12-06-2020 from 4.00 PM**
Last date and time of submission of online bids	**:**	**13-07-2020 at 6.00 PM**
Date and time of opening of Online technical bids	**:**	**14-07-2020 at 11.00 PM**
Cost of the Bid Document	**:**	**Rs. 2000/-**
RISL Processing Fees	**:**	**Rs. 1000/-**
EMD	**:**	**Rs. 20000/-**

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
RAJASTHAN

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS (Ending on 31.03.2022)

"CONFIDENTIALITY IS THE ESSENCE OF THIS BID"

1. LAST DATE FOR RECEIPT OF BIDS, BID FEES, EMD, RISL PROCESSING FEES AND EMPANELMENT FEES

a) E-Bids [In Two Separate Bids (Technical Bid & Price Bid)] Will Be Received Till 06.00 PM on 13-07-2020 By The Rajasthan Medical Services Corporation Ltd, For The Empanelment Of Analytical Testing Laboratories For The Test And Analysis Of DRUGS (Ending on 31.03.2022) in English language. Proposal received after the closing date and time shall not be considered.

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 for another period of 30 days. The Bidder may refuse extension of bid validity without forfeiting the Earnest Money deposit. No refund of tender fee is claimable under any circumstances to any of the bidder.

c) The e-Bids will be received on web-portal of e-procurement of GoR. Every Bidder will be required to pay the Bid form fee Rs. 2000.00 for downloaded from the website, EMD as applicable in Bid condition no. **6** and processing fee of Rs.1000.00 of R.I.S.L. through three separate prescribed challans (***format enclosed in Annexure- I)*** in any branch of the Punjab National Bank Account no. 2246002100024414 throughout country upto 13-07-2020 or through D.D. / bankers cheque in favour of M.D. RMSCL (tender fees and EMD), MD, RISL (tender procession fees) physically in the office of RMSCL by 6.00 PM on 13-07-2020 The bidders shall submit/upload scanned copy of all the challans in Technical Bid**.** Bids will be opened only after ensuring receipt of Bid fees along with processing fees and EMD. **In the absence of Bid fees, processing fees and EMD the Bids will be rejected and will not be opened.**

2. **Eligibility Criteria for Empanelment :-**

(1) Drug Testing Laboratories should have valid Approval for carrying out test on drugs under the Drugs and Cosmetics Act, 1940 and Rules there under. Three years standing in the test & analysis of **drugs/chemicals or food** items and the lab shall be entitled for empanelment for the categories of items for which lab is having approval. Bid is invited from approved Drugs Testing Laboratories situated in India.

(2) The laboratory should be GLP compliant under the provisions of Drugs and Cosmetics Act, 1940 and Rules there under and should hold schedule L-1 certificate or should have approval from Drug Control Department and NABL accreditation with proper scope of accreditation to undertake testing of drugs, surgical and sutures. GLP certificate should be clear, it should not contain ambiguous expressions, like 'by and large'.

(3) The laboratory should have an average annual turnover of **not** less than **Rs. 50 Lakh** for past preceding three years **(2016-17, 2017-18 & 2018-19)**

(4) The lab should have undertaken test and analysis of drugs and supplies of similar nature of at least three government institutions/corporation/reputed manufacturers of drug formulations.

(5) The lab should not stand banned / debarred or blacklisted by any State **or** Central Government Organizations or its central procurement agencies on the due date of bid submission. If a bidder or an approved bidder will be found defaulter for concealing this fact, then following actions may be taken.

(i) Bid rejection

(ii) EMD forfeiture

(iii) Agreement rejection

(iv) S.D. forfeiture

(v) Blacklisting

(6) The laboratory and its responsible persons should not have been convicted under the provisions of applicable laws with regard to the activities and conduct of the laboratory.

(7) The laboratory should have all necessary instruments/equipments/machines for testing of drugs with minimum three functional HPLC's.

3 **TECHNICAL BID**

The Bidder must 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 testing at Annexure-VII). The bidder has to mentioned type of test for each item to be carried out by him, the filled up annexure VII to be submitted with technical bid.

NOTE:- Bidders have to mentioned all the test parameters compulsorily in column no.5 of annexure-VII, If any bidder does not mention any parameter/parameters as narrated in column no. 4, then the bid shall be treated as non-responsive for that particular drug item.

b. The bidders shall submit/upload scanned copy of all the challans in Technical Bid deposited for Bid fees, RISL processing fee and Earnest Money, in case deposited in any branch of PNB throughout country. The required EMD / Tender 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 (tender fees and EMD), MD, RISL (tender procession fees).

c. Attested Photocopy of Analytical approval duly renewed up to date, issued by the State Licensing Authority.

d. **Compliance of Schedule L-1 of Drugs & Cosmetics Rules, 1945 (GLP certificate) and Copy of NABL accreditation with scope for testing of drug formulations.**

e. Documentary evidence of having analysed Drugs, chemicals, foods and other items for the last three years with a statement in the proforma as given in Annexure III.

f. Attested copy of certificate of GST registration.

g. Non- Conviction Certificate by the State Licensing Authority/ competent authority.

h. Annual turnover statement for 3 year i.e. **2016-17, 2017-18 & 2018-19** certified by the practicing Chartered Accountant.

i. Copies of the Balance Sheet and Profit and Loss Account for three years i.e. **2016-17, 2017-18 & 2018-19** duly audited or certified by the practicing Chartered Accountant.

j. The following information in the form given in Annexure IV (a) to IV (d).

   a) The list of permanent technical qualified personnel employed in the laboratory with proof of their qualifications and relevant approvals.

b) The list of sophisticated instruments available in the laboratory.

c) Micro Biological facilities available in the laboratory.

d. List of Reference Samples along with their date of procurement and quantities.

e. In the case of Non- Pharmacopoeial Products the Method of Analysis Should be appended to the Report, especially if the sample is declared as "not of standard quality".

k. A declaration in the proforma given in Annexure V duly signed and Notarized.

l. Details of Laboratory in Annexure – VI.

m. A copy of PAN issued by Income Tax Department.

n. Documentary evidence for the constitution of the company / concern.

o. At any time prior to opening of price bid RMSC either at their own initiate or in response to clarification requested by prospective tender, may modify tender by issuing an amendment. Such amendments shall be loaded on E-Proc site and will be the part of tender.

p. A bidder has to fill up the checklist enclosed at Annexure VIII indicating the infrastructure and testing facilities available in the lab.

4 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 complete tests as applicable to the item. The rate for sterility test for sterile products should also be quoted separately at last entry of BOQ. Any type of uncalled for clarification on prices and or rebates shall not be accepted.**

5 <u>OPENING OF TECHNICAL BID AND FINANCIAL BID EVALUATION</u>

1. There after the Bidders found eligible as stated above on the basis of the examination on technical bid, the financial bid will be opened and after scrutiny thereof, including inspection of the laboratory, if required, the acceptable rates for analysis will be decided and communicated.

6 EARNEST MONEY DEPOSIT

The Earnest Money Deposit shall be Rs. 20,000/- The Earnest Money Deposit 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 up to 13.07.2020 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSC by 6.00 PM on 13.07.2020 Earnest Money Deposit in any other form will not be accepted.

The Bids submitted without sufficient EMD will be summarily rejected. The EMD 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 security deposit.

Government undertaking PSU are exempted for EMD deposition on producing the certificate issued by the competent authority.

7 GENERAL CONDITIONS

1. The details of the Drugs, to be analysed shall be given in **Annexure VII**.
2. The Bidder should quote the rates for complete analysis of each product and name of test to be performed, methodology to be used for each test should be mentioned in **Annexure-VII**. **However wherever rates for individual test are demanded, they should be furnished accordingly in BOQ. Wherever tests are prescribed and their name and methodology for testing are not stated, such lab will not be considered responsive testing for such item.**
3. The rates quoted should be exclusive of taxes.
4. The rates quoted and accepted will be binding on the Bidder for the stipulated period and on no account any revision will be entertained till the completion of the BID period.
5. Analytical Laboratory, which also has its manufacturing activity, if empanelled by RMSC, then Samples of its own manufacturing unit shall not be sent to its empanelled laboratory for testing.
6. The laboratory will not be permitted to outsource any test from other laboratory.
7. RMSCL shall have the right to cause the laboratory to be inspected by the members of its technical committee before opening of price bid and subsequently as and when considered appropriate and based on the finding, the Bidder may be disqualified or de-empanelled, as the case may be.
8. Conditional tender will not be accepted and rejected immediately.

8. 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. The Managing Director, Rajasthan Medical Services Corporation Limited reserves the right to accept or reject any BID for any one or more of the items Bided for, without assigning any reason.
3. The Managing Director, Rajasthan Medical Services Corporation Limited has the right to accept one or more bidders depending on the volume of analytical work.

9. AGREEMENT

1. **The agreement with empanelled laboratories will remain valid up to 31.03.2022. If Required period of contract can be extended upto 3 months same rate, terms and condition without any prior consent and shall be binding on approved bidder.**
2. RMSCL will issue letters of Intent (LOIs) to successful bidders and bidders who are empanelled will have to execute an agreement on a non-judicial stamp paper of value **Rs. 500 /-** (Stamp duty to be paid by the Bidder), in favour of Managing Director, Rajasthan Medical Services Corporation Limited Jaipur within 15 days from the date of receipt of the intimation to them informing that their BIDs have been accepted. The format of agreement will be issued by RMSCL.
3. 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.
4. 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.

10. <u>PERFORMANCE SECURITY</u>

1. The successful Bidders shall be required to pay a security deposit of **Rs. 50,000/-** ***in the form of demand draft*** at the time of execution of the agreement. **Performance security will be refunded three month after expiry of rate contract subject to successful completion of services.**

11. COMPLETE ANALYSIS & REPORTING CONDITIONS

1. (a) On empanelment and entrustment of the job, the Analytical Laboratory should

furnish the test reports within:

i. **10 days from the receipt of the sample in case of Tablets, Capsules, Pessaries, Ointments, Powder and Liquid Oral Preparations (non – sterile products)**

ii. **21 days from the receipt of the sample in the case of I.V. Fluids and injectables and other items requiring test for sterility.**

b) All the tests mentioned in IP/BP/USP/Drugs & Cosmetics Act. etc. including addendus, (as the case may be) should be carried out for each and every sample. The results obtained in the test should be mentioned in numerical value (wherever possible). However this condition will not apply when only specific testing is called for/desired on any particular sample. If any drug is not included in the pharmacopeia at the time of bid opening and letter on it is including in any pharmacopeia the drug should be tested as per pharmacopeia specification.

c) "COMPLIES" or "PASSES" in the result column of the report is treated as incomplete report, if the result has some numerical value.

d) Every test report must have remarks either as "Standard Quality" or "Not of Standard Quality". Any ambiguity/cutting in reports will not be accepted (clear mention of "standard quality or not of standard quality" should be stated in bold letters and crossing/cutting of one of these will not be accepted).

e) Reports should be in A4 size (8.27" X 11.69") paper of good quality.

f) Report should be issued on form 39 and should have S. no. , name of drug sample, code no., batch no., mfg. date, exp. date, description of tests, protocol of test specified & applied, findings & results obtained and should be signed by person-in-charge of testing. In case of Not of Standard Quality Reports the reports shall be release on Pink/Red colored paper for easy identification of NOSQ drugs.

g) Reports should be attached along with Spectra / Chromatography data sheets, if applicable and it will be considered incomplete if spectra or chromatograms are not attached.

2. All test reports of each batch of sample should be submitted to the RMSC in triplicate. In case of failure of a sample, the result should be communicated immediately to the Executive Director (Q.C.) through phone / E-mail and the report should be sent along with protocol.

3. If in any circumstances (like break down of instrument, non-availability of reference standard etc.) the Analytical Laboratory is unable to undertake analysis for a sample, the same should be reported within 24 hours of receipt of such a sample by phone or E-mail and the sample should be returned to the Executive Director (Quality Control), Rajasthan Medical Services Corporation Limited, Jaipur after taking necessary telephonic or mail consent. In case of inability of laboratory to undertake the testing, a penalty of 25% of testing charges applicable for that product / products will be recovered.
4. If placebo or standard test procedure of any product is required the same should be demanded within 48 hours with return request. Period lapsed/taken in providing placebo or standard testing procedure will be condoned from prescribed time limit for that sample.
5. If any sample is received in a damaged condition by the laboratory, the sample should not be analyzed and the information should be sent immediately to the E.D. (Quality Control), Rajasthan Medical Services Corporation Limited Jaipur by Fax or E-mail.
6. The Managing Director, Rajasthan Medical Services Corporation Limited or his authorized representative(s) has / have the right to inspect the laboratories of the Bidders who have submitted BIDs, before taking any decision regarding empanelment. Similarly, the Managing Director, Rajasthan Medical Services Corporation Limited or his authorized representatives may also inspect any empanelled laboratory, at any point of time during the continuance of the BID and terminate / cancel its empanelment or any orders issued to the laboratory, not to entrust any further testing job to the laboratory based on facts brought out during such inspections.
7. The successful lab shall have to make own arrangement for collection of sample, from RMSC Headquarters.
8. It will be sole discretion of RMSC to allot the samples to any empanelled lab in case when there are more than one lab approved for an item. (One or more Laboratories may be empanelled by this tender.)

12. PAYM ENT PROVISIONS

1. No advance payment towards any analysis will be made to the empanelled Bidder.
2. No payment will be made for the incomplete analysis or incomplete report. Deliberate omission of any critical test will be viewed seriously and shall invite action against the laboratory as deemed fit by RMSCL.
3. Payments towards the analysis of Drugs will be made as per approved rate plus tax on it will be along with Tax at the prevailing rate as applicable at the time of payment.

13. PENALTIES

1. If the successful Bidder fails to execute the agreement and payment of security deposit within the time specified or withdraws the BID after intimation of the acceptance of the BID has been sent to or owing to any other reasons, he is unable to undertake the contract, the empanelment will be cancelled and the Earnest Money Deposit deposited by the Bidder shall stand forfeited in favour of the Rajasthan Medical Services Corporation Limited. Such Bidder(s) will also be liable for all damages sustained by the Rajasthan Medical Services Corporation Limited due to of breach of BID conditions. Such damages shall be assessed by the Managing Director, Rajasthan Medical Services Corporation Limited whose decision shall be final.
2. Non performance of any BID or empanelment conditions will disqualify a laboratory to participate in the BID for the period as decided by RMSCL.
3. If it is revealed that the analytical Laboratory is involved in any form of fraud and collusion with the suppliers of Rajasthan Medical Services Corporation Limited, the Analytical Laboratory will be black listed for a period considered suitable. The Bidders shall also be liable for action under criminal law and the matter will be notified to the concerned Director of Drugs Control for suitable action against them under Drugs & Cosmetics Act & Rules.
4. The Managing Director, Rajasthan Medical Services Corporation Limited will be at liberty to terminate without assigning any reasons, the empanelment of any laboratory either wholly or in part at one month's

notice. The Bidder will not be entitled for any compensation whatsoever in respect of such termination.

5. In all matters pertaining to the BID, the decision of the Managing Director, Rajasthan Medical Services Corporation Limited shall be final and binding.

6. (i)If the laboratory requires an extension in time for submission of test report, 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 ***furnishing the test report***.

(ii)The Executive Director (QC)/ Drug Controller/ADC (QC) may extend the testing period with or without liquidated damages in case they are satisfied that the delay in the submission of test reports is on account of any hindrances, he shall apply in writing for extension on occurrence of hindrance but not after the stipulated date of submission of report. Reasons shall be recorded.

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

(a) Delay upto one fourth period of the prescribed testing period; 2.5%

(b) Delay exceeding one fourth but not exceeding half of the prescribed testing period; 5%

(c) Delay exceeding half but not exceeding three fourth of the prescribed testing period; 7.5%

(d) Delay exceeding three fourth of the prescribed testing period; 10%

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

iv. If, at any time during the continuance of this Agreement, the ***laboratory*** has, in the opinion of the Purchaser, delayed in submitting any test report, by the reasons of any riots, mutinies, wars, fire, storm, earthquakes, tempest or other exceptional cause, on a specific request made by the laboratory, the time for submitting test report may be extended by the ***RMSCL*** purely at his discretion for such period as may be considered reasonable. No further representation from the ***laboratory*** will be entertained on this account.

14. 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.

15. GRIEVANCE REDRESSAL DURING EMPANELMENT 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 empanelment;

(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 empanelment 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.

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

Any person participating in a empanelment 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.

17. 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.

18. <u>JURISDICTION</u>

1. In the event of any legal dispute arising out of the BID such dispute would be subject to the jurisdiction of the Civil courts within the city of Jaipur only.

Managing Director
Rajasthan Medical Services Corporation

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. 2 (3), 3(h)

ANNUAL TURN OVER STATEMENT

The Annual Turnover 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 Lacs (Rs)
1	2016-17	
2	2017-18	
3	2018-19	
Total		**Rs.** **Lacs**
Average turnover per annual		**Rs.** **Lacs**

Date:

Seal:

Siganture of Auditor/
Chartered Accountant
(Name in Capital)

ANNEXURE III
Ref. Clause No: 3 (e)

PROFORMA FOR PERFORMANCE STATE MENT
(for a period of last 3 years)

Name of the Laboratory : _____

Address:_____

_____

_____

Types of Samples Analysed No. of Samples Analysed during

(2016-17, 2017-18 and 2018-19)

01. Tablets / Capsules / Pessaries/Dry Powders

02. Injectables

03. Liquid Preparations

04. Ointments / Creams / Gels

05. Others (Specify)

06. Surgicals (Specify item names)

07. Sutures (Specify types)

08. Implants

09. Devices

Signature :
Date :
Name of the Lab :
Office Seal :

ANNEXURE – IV (a)
Ref. Clause No: 3 (j) (a)

PERSONNEL IN QC DEPARTM ENT

Name of the Technical Staff approved by State Licensing Authority along with his Designation, Highest Qualification, Experience (Experience relevant to analysis of drugs/surgical/sutures)

Signature :

Date :

Nam e of the Lab :

Office Seal :

ANNEXURE – IV (b)
Ref. Clause No: 3(j) (b)

LIST OF SOPHISTICATED EQUIPMENT/INSTRUMENT/APPARATUS AVAILABLE IN THE LAB

S.No.	Name of the Equipment Instruments / Apparatus	Make & Description	Date of Installation	Date of last Validation	Approved for testing of drugs from State licensing Authority since……..

Signature :

Name of the Lab :

Date :

Official Seal:

ANNEXURE – IV (C)
Ref. Clause No: 3(j) (c)

FACILITIES IN THE MICROBIOLOGICAL SECTION

I. LIST OF STOCK CULTURES AVAILABLE

II. LIST OF EQUIPMENT / APPARATUS AVAILABLE WITH DATE OF INSTALLATION, make and approval from State Licensing Authority to permit microbiological testing in the Lab.

Signature :

Name of the Lab :

Date :

Official Seal:

ANNEXURE – IV (d)
Ref. Clause No: 3(j) (d)

LISTOF REFERENCES SAMPLES ALONG WITH THEIR DATE OF PROCUREMETN AND QUANTITIES

Signature :

Name of the Lab :

Date :

Official Seal:

Affidavit

(on Non Judicial Stamp of Rs.500/-)

ANNEXURE – V
Ref. Clause No: 3(k)

DECLARATION FORM

1. I (Name of the Bidder) S/O_____, Age_____, resident of_____, am proprietor /Partner/Director having our office at_____ and the approved drug testing laboratory at_____do hereby declare that I have carefully read all the conditions of BID of Rajasthan Medical Services Corporation Ltd., Jaipur, for the BIDs floated for empanelment of approved drugs testing laboratories for analysis of drugs. (ending on 31.03.2022) and shall abide by all the conditions set forth therein.
2. I further declare that I possess valid approval for testing of all the drugs/surgicals & sutures for which Price Bid have been submitted by me/us in Cover B and permission on Form 37 have been obtained for testing of these items from State Licensing Authority where ever applicable.
3. That the approval to test drugs/surgical & sutures have been obtained on Form 37 bearing No._____which is valid/renewed up to_____.
4. That the Bidder firm is a proprietorship/Partnership/Pvt. Ltd./ltd. firm and following are the other partners/directors:-

S.No.	Name of Partner/Director	Age	Present & Permanent Address

5. That our laboratory/Firm/Company does not stand blacklisted /debarred or banned on any ground either by Bid Inviting Authority or Govt. of Rajasthan on the date of bid submission.

   Our laboratory/Firm/Company also does not stand blacklisted, debarred or banned on the ground of **wrong reporting of test results** or on the ground of submission of fake or forged documents or false information / facts, by any State or Central Government or by its central drug procurement agencies, on the date of bid submission for supply of drugs/medicines in India.

That I/We have carefully read all the conditions of bid in Ref. No.**:** F.02(283)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-08/2020/990 Dated :1106.2020

6. For the empanelment of analytical testing laboratories for the test and analysis of DRUGS (Ending on 31.03.2022) for Rajasthan medical services corporation and accept all conditions of bid, including amendments if any.

7. I/ we hereby declare under Section 7 of Rajasthan Transparency in Public Procurement Act, 2012. that:
    a. I/we possess the necessary professional, technical, financial and managerial resources and competence required by the Bidding Document issued by the Procuring Entity;
    b. 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;
    c. 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;
    d. 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;
    e. l/we do not have a conflict of interest as specified in the Act, Rules and the Bidding Document, which materially affects fair competition;

8. Our complete address for communication with phone no.:- ----------
---
---

9. E mail address :- ----------

10. Bank detail for e banking :-

    Name of account holder ……

(Affidavit Page2)

    Full name of Bank with Branch ……

    A/c no. with full digits……..

    IFSC code ……..

(Deponent)

Signature :

Date :

Name of the Lab :

Office Seal :

Verification

I……..S/o……(Designation)…….

Affirm on oath that the contents/information from para 1 to 10 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 and forfeiting the earnest money deposit and or performance security, for which I shall be solely responsible and the laboratory / firm may be Debarred/Banned/ prosecuted for the same

(Name of Deponent & Signature)

ATTESTED BY NOTARY PUBLIC

ANNEXURE – VI
Ref.Clause No: 3

(l)

DETAILS OF LABORATORY

1. Name of the Laboratory & Full Address :

   Phone No (landline) :

   Fax :

   E-mail :

2. Other Branches & their Address (if any) :

3. Whether the firm has it own manufacturing unit? :

   If yes give details of address, license number etc.

4. Date of Inception :

5. Approval No. & Date :

6. Issued by :

7. Valid up to :

8. Schedule L-1 certificate its no. and date of issue (GLP) :

   or

9. (i) NABL Accreditation no. & date
   (ii) Scope of Accreditation
   (iii) Its validity.

10. Name of the authorized signatory :

11. Specimen Signature of the authorized Signatory :

12. Names & Specimen Signatures of the Approved technical Staff who are authorized to sign the test reports :

ANNEXURE –VII
Ref: Clause no. 3 (a),7(1)

NOTE:- Bidders have to mentioned all the test parameters compulsorily in column no.5 (Agree to perform test parameters), If any bidder does not mention any parameter/parameters as narrated in column no. 4, then the bid shall be treated as non-responsive for that particular drug item.

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
1	172	Enoxaparin Sodium Injection IP 60 mg	Description	
			Identification A (Chemical)	
			Identification B (by UV)	
			Identification C (Chemical)	
			PH	
			Benzyl Alcohol (If Present)	
			Free Sulphate (Ion Chromatography)	
			Bacterial endotoxins	
			Extractable volume	
			Particulate matter	
			Assay: (Anti Factor Xa activity)	
			(Anti Factor IIa activity)	
			Anti factor Xa to Anti Factor Iia ratio	
			Sterility	
2	188	Clopidogrel Tablets IP 75 mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
			Identification of colour	
3	235	Gadodiamide Injection 0.5 mmol/ml Vial	Description	
			Identification A (by UV)	
			Identification B (by HPLC)	
			Organic impurities (by HPLC)	
			Osmolality and Osmolarity	
			pH	
			Particulate contamination	
			Bacterial endotoxins	
			Extractable volume	
			Assay: (by HPLC)	
			Sterility	
4	244	Compound Benzoin Tincture IP	Description	
			Identification A- (By TLC)	
			Identification B- (By TLC)	
			Identification C- (By TLC)	
			Identification D- (By TLC)	
			Weight per ml	
			Ethanol Content	
			Total Solid	
			Contents of Packaged dosage Forms: Container Content	
			Assay (chemical)	
5	281	Carboprost Tromethamine Injection Each ml contains Carboprost 0.25mg/ml	Description	
			Identification by IR	
			pH	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Bacterial endotoxins	
			Particulate matter	
			Extractable volume	
			Assay by HPLC	
			Sterility (by MF)	
6	284	Conjugated Estrogen Tablets USP 0.625 mg.	Description	
			Identification A (by GC)	
			Identification B (by GC)	
			Average weight	
			Dissolution (By HPLC)	
			1st Stage	
			2nd stage	
			3rd Stage	
			4th Stage	
			Uniformity of content (byHPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by GC)	
7	423	Hyaluronidase Injection IP Each vial contains Hyaluronidase IP 1500 I.U.	Description	
			Identification A (by Chemical)	
			Identification B (Performed on animals)	
			pH	
			Average Weight	
			Uniformity Of weight	
			Clarity of solution test a and b	
			Appearance of solution	
			Particulate matter	
			Bacterial endotoxins	
			Assay: Phenobarbital sodium (by UV)	
			Sterility	
8	694	Inj. Butorphanol tartrate USP 1mg/ml 1ml Size	Description	
			Identification (by TLC)	
			pH	
			Becterial endotoxins	
			Particulate matter (by Particle counter)	
			Volume in container	
			Assay: (by HPLC)	
			Sterility	
9	695	Inj. Diclofenac Sodium aqueous 75mg/ml 1ml Size, IV & IM use	Description	
			Identification (by TLC)	
			pH	
			Particulate matter	
			Extractable volume	
			Assay: (by HPLC)	
			Sterility	
10	696	Paracetamol Infusion IP 1%w/v 100ml Size	Description	
			Identification (by HPLC)	
			pH	
			Light absorption (by UV)	
			Related substances (by HPLC)	
			Becterial endotoxins	
			Particulate matter (by Particle counter)	
			Extractable volume	
			Assay: (by HPLC)	
			Sterility	
11	697	Tab. Ketorolac 10 mg, IP	Description	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Identification (by HPLC)	
			Average weight	
			Dissolution (by UV)	
			Uniformity of content (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
12	698	Tab. Baclofen 10 mg, IP (Each Uncoated Tablet contains Baclofen IP 10 mg)	Description	
			Identification A (by TLC)	
			Identification B (by HPLC)	
			Average weight	
			Lactam (by HPLC)	
			Dissolution (by HPLC)	
			Uniformity of content (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
13	699	Tab. Tizanidine Hydrochloride 2mg IP (Each Uncoated Tablets contains Tizanidine Hydrochloride IP 2 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Dissolution (by UV)	
			Uniformity of content (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
14	700	Tab. Dexamethasone IP 4 mg (Each Uncoated Tablet contains Dexamethasone IP 4 mg)	Description	
			Identification A (by IR)	
			Identification B (by HPLC)	
			Identification C (Chemical)	
			Average weight	
			Related substances (by HPLC)	
			Uniformity of content (by HPLC)	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
15	**701**	Tab Lamotrigine IP 50 mg (Each Sustained Release Tablets contains Lamotrigine IP 50 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Related substances (by HPLC)	
			Uniformity of weight	
			Uniformity of content (by HPLC) if tablets other than film coated	
			Dissolution: (BYHPLC)	
			1st stage	
			2nd stage	
			3rd stage	
			4th stage	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
16	702	Tab Divalproex Extended Release IP 250 mg (Each Extended Release Film Coated Tablet contains Divalproex Sodium IP Equivalent to Valproic acid 250 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution:	
			1st stage	
			2nd stage	
			3rd stage	
			4th stage	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
17	703	Tab. Oxcarbazepine IP 150 mg (Each Film Coated Tablet contains Oxcarbazepine IP 150 mg)	Description	
			Identification A (by HPLC)	
			Identification B (by UV)	
			Average weight	
			Related substances (by HPLC)	
			Uniformity of weight	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
18	704	Tab. Lacosamide 100 mg (Each Film Coated Tablet contains Lacosamide 100 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
19	705	Tab Topiramate IP 25 mg (Each Film Coated Tablet contains Topiramate IP 25 mg)	Description	
			Identification A (by IR)	
			Identification B (by HPLC)	
			Average weight	
			Related substances (by HPLC)	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
20	706	Tab. Amoxycillin 250 mg + Calvulanic Acid 125 mg IP (Each Film Coated Tab. Contain Amoxycillin Trihydrate IP 250 mg & Potassium Clavulanate IP 125 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Water	
			Uniformity of content: Clavulanic acid (by HPLC)	
			Dissolution:	
			Amoxycillin (by HPLC)	
			Clavulanic acid (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay:	
			Amoxycillin (by HPLC)	
			Clavulanic acid (by HPLC	
21	707	Inj. Piperacillin 2 gm + Tazobactom 250mg USP	Description	
			Identification (by HPLC)	
			Identification (by HPLC)	
			pH	
			Related substances (by HPLC)	
			Water	
			Bacterial endotoxins	
			Average net content	
			Uniformity of weight	
			Clarity of solution test a and b	
			Particulate matter	
			Assay:	
			Piperacillin (by HPLC)	
			Tazobactum (by HPLC)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Sterility	
22	708	Inj. Ceftriaxone 1 gm + Tazobactum 1.25 gm	Description	
			Identification of:	
			Ceftriaxone (by HPLC)	
			Tazobactum (by HPLC)	
			Average net content	
			Uniformity of weight	
			pH	
			Related substances (by HPLC)	
			Water	
			Clarity of solution test a and b	
			Particulate matter	
			Bacterial endotoxins	
			Assay:	
			Ceftriaxone (by HPLC)	
			Tazobactum (by HPLC)	
			Sterility	
23	709	Tab. Cefadroxil 250 mg	Description	
			Identification (by TLC)	
			Average weight	
			Related substances (by HPLC)	
			Uniformity of weight	
			Dissolution (by UV)	
			Water	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
24	710	Tab. Cefadroxil 500 mg	Description	
			Identification (by TLC)	
			Average weight	
			Related substances (by HPLC)	
			Uniformity of weight	
			Dissolution (by UV)	
			Water	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
25	711	Ofloxacin Oral Suspension IP (Each 5ml contains Ofloxacin IP 100 mg) 30 ml Size	Description	
			Identification (by HPLC)	
			Contents of Packaged Dosage Forms	
			Weight per ml	
			Assay: (by HPLC)	
			Identification of colour	
			Microbial Examination	
			Total aerobic count	
			Total fungal count	
			E. coli	
26	712	Tab. Levofloxacin IP 500 mg (Each Film Coated Tablet containsLevofloxacin Hemihydrate IP 500 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
			Identification of colour	
27	713	Tab. Faropenem Sodium 200 mg	Description	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
		(Each Film coated Tablet contains Faropenem Sodium equivalent to Faropenem Sodium 200 mg)	Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
28	714	Inj. Clindamycin phosphate IP 300 mg	Description	
			Identification A (by TLC)	
			Identification B (by HPLC)	
			pH	
			Related substances (by HPLC)	
			Becterial endotoxins	
			Particulate matter	
			Extractable volume	
			Assay: (by HPLC)	
			Sterility	
29	715	Inj. Imipenem + Cilastatin 500mg/500mg IP Powder for Solution	Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			pH	
			Clarity of solution test a and b	
			Particulate matter	
			Bacterial endotoxins	
			Loss on drying	
			Assay: (by HPLC)	
			Sterility	
30	716	Inj. Polymixin Sulphate B USP 5 Lac I.U.	Description	
			Constituted solution(clarity of Solution)	
			Identification (by TLC)	
			Pyrogen	
			Average net content	
			Uniformity of weight	
			Particulate matter in Injection	
			Residue on ignition	
			Assay: (by microbial)	
			Sterility	
31	717	Inj. Meropenem IP 250 mg	Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			pH	
			Related Substances (by HPLC)	
			Content of Sodium (by FP/AAS)	
			Bacterial endotoxins	
			Loss on drying	
			Clarity of solution test a and b	
			Particulate matter	
			Assay: (by HPLC)	
			Sterility	
32	718	Inj. Colistimethate IP 1M IU Powder for Solution	Description	
			Identification A (by TLC)	
			Identification B (Chemical)	
			Identification C (Chemical)	
			Identification D (Chemical)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Average net content	
			Uniformity of weight	
			pH	
			free colistin	
			Bacterial endotoxins	
			Loss on drying	
			Clarity of solution test a and b	
			Particulate matter	
			Assay: (by Microbiological assay)	
			Sterility	
33	719	Inj. Liposomol Amphotericine B 10 mg	Description	
			pH	
			Loss on drying	
			Bacterial endotoxins	
			Average weight	
			Uniformity of weight	
			Particulate matter	
			Clarity of solution A and B	
			Assay: (by Microbiological assay)	
			Sterility	
34	720	Inj. Voriconazole 200mg/Vial	Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			pH	
			Related substances (by HPLC)	
			Bacterial endotoxins	
			Clarity of solution test a and b	
			Particulate matter	
			Assay: (by HPLC)	
			Sterility	
35	721	Tab. Terbinafine Hydrochloride IP 250 mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Limit of Terbinafine Dimer (by HPLC)	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
36	722	Tab. Valganciclovir 450 mg	Description	
			Identification (by HPLC)	
			Identification (by UV)	
			Average weight	
			Uniformity of weight	
			Organic Impurities (By HPLC)	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
37	723	Tab. Entecavir IP 0.5 mg (Each Film Coated Tablet contains Entecavir IP 0.5 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of content (by HPLC)	
			Related substances (by HPLC)	
			Dissolution (by HPLC)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
38	724	Inj. Ganciclovir Sodium 500mg IP (lyophilized powder for reconstitution)	**Ganciclovir Injection IP**	
			Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			pH	
			Water	
			Bacterial endotoxins	
			Clarity of solution test a and b	
			Particulate matter	
			Assay: (by HPLC)	
			Sterility	
39	725	Capsule Procarbazine Hydrochloride USP 50 mg (Each Capsule contains Procarbazine Hydrochloride USP 50 mg)	**Procarbazine hydrochloride capsules IP**	
			Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by Polarographic Potential)/ HPLC	
40	726	Inj. Bendamustine 100 mg	**Bendamustine Injection IP**	
			Description	
			Identification A (by HPLC)	
			Identification B (Chemical)	
			Average net content	
			Uniformity of weight	
			pH	
			Water	
			Related substances (by HPLC)	
			Bacterial endotoxins	
			Clarity of solution test a and b	
			Particulate matter	
			Assay: (by HPLC)	
			Sterility	
41	727	Tab. Capecitabine IP 500 mg (Each Film Coated Tablet contains Capecitabine IP 500 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
42	728	Tab. Letrozole USP 2.5 mg (Each Film Coated Tablet contains Letrozole USP 2.5 mg)	**Letrozole Tablets IP**	
			Description	
			Identification A (by TLC)	
			Identification B (by HPLC)	
			Average weight	
			Uniformity of content (by HPLC)	
			Dissolution (by HPLC)	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Assay: (by HPLC)	
43	729	Capsule Temozolomide IP 100 mg (Each hard Gelatin Capsule contains Temozolomide IP 100mg)	Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
44	730	Inj. Bortezomib 2mg	**Bortezomib Injection IP**	
			Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			Appearance of solution	
			pH	
			Related substances (by HPLC)	
			Tertiary Butanol (by GC) if present	
			Bacterial endotoxins	
			Clarity of solution test a and b	
			Particulate matter	
			Assay: (by HPLC)	
			Sterility	
45	731	Tab Abiraterone Acetate IP 250 mg (Each Uncoated Tablet contains Abiraterone Acetate IP 250 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
46	732	Capsule Lomustine IP 40 mg (Each Capsule contains Lomustine IP 40 mg)	Description	
			Identification A (by IR)	
			Identification B (by Melting point)	
			Average net content	
			Uniformity of weight	
			Related substances (by TLC)	
			Related substances (by HPLC)	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by UV)	
47	733	Cap Thalidomide USP 100 mg (Each Hard Gelatin Capsule contains Thalidomide USP 100 mg)	Description	
			Identification A (by TLC)	
			Identification B (by HPLC)	
			Average net content	
			Uniformity of dosage unit (Weight Variation)	
			Dissolution (By HPLC)	
			Organic Impurities (By HPLC)	
			Assay: (By HPLC)	
			Microbial enumeration tests and tests for specified Microorganisms	
			Total aerobic count	
			Total Combined molds and yeasts counts	
			E. coli	
48	734	Inj. Bevacizumab 400 mg	**NIB**	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
49	735	Inj. Bevacizumab 100 mg	**NIB**	
50	736	Tab. Cyclophosphamide IP 50 mg (Each Sugar Coated Tablet contains Cyclophosphamide IP 53.5 mg equivalent to Anhydrous Cyclophosphamide 50 mg)	Description	
			Identification A (by IR)	
			Identification B (Chemical)	
			Identification C (Chemical)	
			Average weight	
			Uniformity of Weight	
			Acidity	
			Disintegration test	
			Related substances (by TLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by Titration)	
51	737	Tab. Gefitinib IP 250 mg (Each Film Coated Tablet contains Gefitinib IP 250 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
52	738	Capsule Mycophenolate mofetil USP 250 mg (Each Capsule Contain Mycophenolate mofetil USP 250 mg)	**Mycophenolate mofetil Capsules IP**	
			Description	
			Identification A (by HPLC)	
			Identification B (by UV)	
			Average net content	
			Limit of degradation product (by HPLC)	
			Uniformity of weight	
			Related substances (by HPLC)	
			Limit of Z-Mycophenolate mofetil (HPLC)	
			Dissolution (by HPLC)	
			Water	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
53	739	Capsule Tacrolimus IP 0.5 mg (Each Hard Gealtin Capsule Tacrolimus IP 0.5 mg)	Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			Related substances (by HPLC):	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
54	740	Tab. Mycophenolate Sodium 360 mg (Each Enteric Coated tablet Contain Mycophenolate Sodium 360 mg)	Description	
			Identification (by HPLC)	
			Identification (by UV)	
			Average weight	
			Uniformity of content (by HPLC)	
			Disintegration test /Dissolution (By UV)	
			Organic Impurities (By HPLC)	
			Z-Mycophenolate mofetil	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
55	741	Tab. Bicalutamide USP 50 mg (Each Film Tablet contains Bicalutamide USP 50 mg)	**Bicalutamide Tablets IP**	
			Description	
			Identification (by HPLC)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Dissolution (by UV)	
			Water	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
56	742	Tab. 6 Thioguanine USP 40 mg (Each Uncoated Tablet contains 6 Thioguanine USP 40 mg)	**6 Thioguanine Tablets IP**	
			Description	
			Identification A (by IR)	
			Identification B (by HPLC)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
57	743	Inj. Zoledronic acid IP 4mg/100ml 100ml Size	**Zoledronic acid Injection IP (Powder form instead of liquid)**	
			Description	
			Identification (by HPLC)	
			Average net content	
			Uniformity of weight	
			pH	
			Bacterial endotoxins	
			Clarity of solution test a and b	
			Particulate matter	
			Assay: (by HPLC)	
			Sterility	
58	744	Inj. n Butyl Alcohol 0.26mg/5ml, Citric Acid 2.5mg/5ml, and Sod. Chloride Solution 5 ml Size	Description	
			Identification of:	
			n-Butyl Alcohol (by GLC)	
			Citric Acid	
			Sodium and Chloride	
			pH	
			Particulate matter	
			Extractable volume	
			Assay:	
			n-Butyl Alcohol (by GLC)	
			Citric Acid (by Ion Chromatography)	
			Sodium Chloride (by Titration)	
			Sterility	
59	745	Tab Ethamsylate BP 500 mg (Each Uncoated Coated Tablets contains Ethamsylate BP 500 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
60	746	Feracrylum 1%w/w Sterile Solution 100 ml	Description	
			Identification of Feracrylum (Chemical)	
			pH	
			Relative Viscosity at 25c	
			Unreacted Protein	
			Activity of Fearcrylum	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Content of Iron	
			Extractable volume	
			Assay: (by Titration)	
			Sterility	
61	747	Inj. Tranexamic Acid IP 100mg/ml 5ml Size	Description	
			Identification A (by IR)	
			Identification B (Chemical)	
			pH	
			Related substances (by HPLC)	
			Bacterial endotoxins	
			Particulate matter	
			Extractable volume	
			Assay: (by Titration)	
			Sterility	
62	748	Recombinant FIX 500 IU with diluent	**NIB**	
63	749	3rd Generation Recombinant F VIII 250 IU with diluent	**NIB**	
64	750	3rd Generation Recombinant F VIII 1000 IU with diluent	**NIB**	
65	751	Tab. Clonidine Hydrochloride USP 0.1 mg (Each Tablet contains Clonidine Hydrochloride USP 0.1 mg)	**Clonidine Hydrochloride Tablets IP**	
			Description	
			Identification A (by UV)	
			Identification B (Chemical)	
			Average weight	
			Uniformity of content (by UV)	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
66	752	Tab. Sotalol Hydrochloride USP/BP 40mg (Each Film Coated Tablet contains Sotalol Hydrochloride USP/BP 40mg)	Description	
			Identification (by UV)	
			Identification (by TLC)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
67	753	Inj. Esmolol hydrochloride 10mg/ml 10ml Size	**Esmolol hydrochloride Injection IP**	
			Description	
			Identification (by HPLC)	
			pH	
			Bacterial endotoxins	
			Particulate matter	
			Extractable volume	
			Assay: (by HPLC)	
			Sterility	
68	754	Inj. Sodium Nitroprusside 25mg/ml 2ml Size	**Sodium Nitroprusside Injection IP**	
			Description	
			Identification A (by UV)	
			Identification B (Chemical)	
			Identification C (Chemical)	
			Bacterial endotoxins	
			Particulate matter	
			Extractable volume	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Assay: (by HPLC)	
			Sterility	
69	755	Tab. Carvedilol 3.125 mg	**Carvedilol Tablets IP**	
			Description	
			Identification (by HPLC)	
			Average weight	
			Dissolution (by HPLC)	
			Uniformity of content (by HPLC)	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
70	756	Tab. Rosuvastatin IP 20 mg (Each Film Coated Tablet contains Rosuvastatin Calcium IP equivalent to Rosuvastatin 20 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Dissolution (by HPLC)	
			Uniformity of weight	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
71	757	Tab. Rosuvastatin 10 mg	Description	
			Identification (by HPLC)	
			Average weight	
			Dissolution (by HPLC)	
			Uniformity of content (by HPLC)	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
72	758	Tab. Sacubitril 24 mg and Valsartan 26 mg	Description	
			Identification of:	
			Sacubitril (by HPLC)	
			Valsartan (by HPLC)	
			Average weight	
			Uniformity of content (by HPLC)	
			Sacubitril (by HPLC)	
			Valsartan (by HPLC)	
			Disintegration test	
			Assay: (by HPLC)	
			Sacubitril (by HPLC)	
			Valsartan (by HPLC)	
			Identification of colour	
73	759	Powder Clotrimazole 1%w/w 30 gm	Description	
			Identification (by HPLC)	
			Content of 2-Chlotritanol (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
74	760	Oint. Terbinafine 1%w/w (10 gm Tube)	**Terbinafine Cream IP**	
			Description	
			Identification (by HPLC)	
			pH	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
75	761	Olopatadine Hydrochloride Ophthalmic Solution 0.1% w/v USP (E/D) 5ml Size	**Olopatadine Hydrochloride Ophthalmic Solution IP**	
			Description	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Identification (by HPLC)	
			pH	
			Related substances A (by HPLC)	
			Related substances B (by HPLC)	
			Contents of Packaged Dosage Forms	
			Sterility	
			Assay: (by HPLC)	
76	762	Cream Mupirocin USP 2% (Each Gram contains 21.5 mg Mupirocin Calcium USP in a mineral oil cream base) 15 gm Size	**Mupirocin Ointment IP**	
			Description	
			Identification A (by TLC)	
			Identification A (by HPLC)	
			Minimun fill	
			pH	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
			Microbial enumeration test	
77	763	Tab Doxylamine Succinate 20 mg & Pyridoxine Hydrochloride 20 mg (Each Enteric Coated Tablet contains Doxylamine Succinate USP 20 mg & Pyridoxine Hydrochloride IP 20 mg)	Description	
			Identification of:	
			Doxylamine Succinate (by HPLC)	
			Pyridoxine hydrochloride (by HPLC)	
			Average weight	
			Uniformity of content (by HPLC)	
			Doxylamine Succinate	
			Pyridoxine hydrochloride	
			Disintegration test	
			Assay: (by HPLC)	
			Doxylamine Succinate	
			Pyridoxine hydrochloride	
			Identification of colour	
78	764	Inj. Prochlorperazine mesylate 12.5mg/ml 5ml Size	Description	
			Identification A (by IR)	
			Identification B (Chemical)	
			pH	
			Related substances (by TLC)	
			Particulate matter	
			Extractable volume	
			Assay: (by UV)	
			Sterility	
79	765	Probiotic Sachets 1 gm Size (Each Gram Sachet contains Saccharomyces Boulardii 250mg & Lactic acid Bacillus 150 million spores)	Description	
			Identification of:	
			Saccharomyces Boulardii	
			Lactic acid Bacillus	
			Average net content	
			Uniformity of weight	
			Contents of Packaged Dosage Forms	
			Assay: (by Microbiological assay)	
			Saccharomyces Boulardii	
			Lactic acid Bacillus	
80	766	Tab. Mesalamine USP 1.2 gm Enteric Coated (Each Enteric Coated Prolonged Release Tablet Contain Mesalamine USP 1.2 gm)	**Mesalamine Prolonged Release Tablets IP**	
			Description	
			Identification (by IR)	
			Average weight	
			Related substances (by HPLC)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Impurities A and C (by HPLC)	
			Impurities K (by HPLC)	
			Uniformity of weight	
			Dissolution:	
			Acid stage	
			Buffer stage	
			1st stage	
			2nd stage	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
81	767	Inj. Hepatitis B Immunologlobin IP 100 I.U	**NIB**	
82	768	Inj. Cis Atracurium Besylate 2 mg/ml in 5 ml vial	**Atracurium Besylate Injection IP**	
			Description	
			Identification (by HPLC)	
			pH	
			Related substances (by HPLC)	
			Extractable volume	
			Particulate matter	
			Bacterial endotoxins	
			Assay: (by HPLC)	
			Sterility	
83	769	Acyclovir Eye Ointment IP 3%w/w 5gm Size	Description	
			Identification A (by UV)	
			Identification B (by TLC)	
			Guanine (by TLC)	
			Uniformity of weight	
			Assay: (by UV)	
			Sterility	
84	770	Eye drop Moxifloxacin 0.5%w/v Ophthalmic Solution IP 5ml Size	Description	
			Identification (by HPLC)	
			pH	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
			Sterility	
85	771	Chloramphenicol 1%w/w Eye ointment IP, 3gm Size	Description	
			Identification A (by IR)	
			Identification B (Chemical)	
			Minimun fill	
			Uniformity of weight	
			Assay: (by HPLC)	
			Sterility	
86	772	Natural Micronised Progesteron Soft gelatin Capsule 200 mg (Each Soft Gelatin Capsule contains Progesteron IP 200 mg)	Description	
			Identification A (by HPLC)	
			Uniformity of content (by HPLC)	
			Disintegration test	
			Uniformity of weight	
			Assay: (by HPLC)	
			Microbial enumeration test	
87	773	Tab Cabergoline IP 0.5mg (Each Uncoated Coated Tablet contains abergoline IP 0.5mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Dissolution (by HPLC)	
			Uniformity of content (by HPLC)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
88	774	Inj. Human Chorionic Gonadotropin IP 5000 I.U.	**NIB**	
89	775	Leurprolide Acetate depot 3.75 mg	Description	
			Identification (by HPLC)	
			Water	
			pH	
			Extractable volume	
			Particulate matter	
			Bacterial endotoxins	
			Related substances (by HPLC)	
			Average weight	
			Uniformity of weight	
			Uniformity of content (by HPLC)	
			Assay: (by HPLC)	
			Sterility	
90	776	Leurprolide Acetate depot 11.25 mg	Description	
			Identification (by HPLC)	
			Water	
			Extractable volume	
			Particulate matter	
			Bacterial endotoxins	
			pH	
			Related substances (by HPLC)	
			Assay: (by HPLC)	
			Sterility	
91	777	Tab. Levosulpiride 25 mg (Each uncoated Tablet contains Levosulpiride 25 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight or	
			Uniformity of content (by HPLC)	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
92	778	Tab. Lorazepam IP 2 mg (Each Uncoated Tablet contains Lorazepam IP 2 mg)	Description	
			Identification A (by UV)	
			Identification B (by TLC)	
			Average weight	
			Dissolution (by UV)	
			Uniformity of content (by UV)	
			Related substances (by TLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by UV)	
93	779	Tab. Zolpidem 5 mg	Description	
			Identification A (by IR)	
			Identification B (by HPLC)	
			Average weight	
			Dissolution (by HPLC)	
			Uniformity of content (by HPLC)	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
94	780	Tab. Acebrophylline 100 mg	Description	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Identification of (by HPLC)	
			Acephylline	
			Ambroxol	
			Average weight	
			Disintegration test	
			Uniformity of weight	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
			Acephylline	
			Ambroxol	
95	781	Ringer Acetate Infusion 500 ml		
			Description	
			Identification A (Chemical)	
			Identification B (Chemical)	
			Identification C (Chemical)	
			Identification D (Chemical)	
			Identification E (Chemical)	
			pH	
			Particulate contamination (by particle counter)	
			Extractable volume	
			Bacterial endotoxins	
			Heavy Metals	
			Sterility	
			Assay:	
			Total Chloride	
			Sodium	
			Potassium	
			Calcium	
96	782	Sodium Chloride 0.45%w/v Polypack 500 ml	Description	
			Identification A (Chemical)	
			Identification B(Chemical)	
			Heavy metals	
			pH	
			Particulate contamination (by particle counter)	
			Extractable volume	
			Bacterial endotoxins	
			Assay: (Titration)	
			Sterility	
97	783	Tab. Savelamer Carbonate 400 mg (Each Film Coated Tablet contains Savelamer Carbonate 400 mg)	Description	
			Identification A (by HPLC)	
			Average weight	
			Uniformity of weight	
			Disintegration time	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
			Identification of colour	
98	784	Tab Sodium Bicarbonate USP 1 gm (Each Film Coated Tablets contains Sodium Bicarbonate USP 1 gm)	Description	
			Identification (by Chemical)	
			Identification (by Chemical)	
			Disintegration	
			Average weight	
			Uniformity of dosage unit (weight variation)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Assay: (by Titration)	
99	785	Tab. Levamisol Hydrochloride IP 50 mg (Each Uncoated tablet contain levamisol Hydrochloride IP 50 mg)	Description	
			Identification (by HPLC)	
			Average weight	
			Dissolution (by UV)	
			Uniformity of weight	
			Related substances (by TLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by Titration)	
100	786	Tab. Phenazopyridine 5 mg	**Phenazopyridine Tablets USP**	
			Description	
			Identification A (by UV)	
			Identification B (by HPLC)	
			Average weight	
			Organic Impurities (By HPLC)	
			Content uniformity (by HPLC)	
			Dissolution (by UV)	
			Assay: (By HPLC)	
101	787	Tab. Dutasteride 0.5 mg	**Dutasteride Capsules IP**	
			Description	
			Identification (by HPLC)	
			Average weight	
			Dissolution (by HPLC)	
			Related substances (by HPLC)	
			Uniformity of content (by HPLC)	
			Assay: (By HPLC)	
102	788	Syp. Alkylizer 1.4 gm/5 ml (100 ml) (Disodium Hydrogen Citrate)	Description	
			Identification of sodium and citrate	
			Weight per ml	
			pH	
			Contents of Packaged Dosage Forms	
			Assay: (by Titration)	
			Identification of colour	
			Microbial Examination	
			Total aerobic count	
			Total fungal count	
			E. coli	
103	789	Inj. Ferric Carboxymaltose 50 mg/ml 10 ml size	Description	
			Identification B (by Chemical)	
			Identification C (by Chemical)	
			pH	
			Weight per ml	
			Average Molecular Weight (By GPC)	
			Limit for Iron(ii) (By Titrimetry)	
			Poly maltose Content (by UV)	
			Chloride Content (By Titrimetry)	
			Sodium Content	
			Osmolarity	
			Becterial endotoxins	
			Particulate matter (by Particle counter)	
			Extractable volume	
			Assay: (by HPLC)	
			Sterility	
104	790	Multi vitamin Syrup	Description	
			pH	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Contents of Packaged Dosage Forms	
			Assay:	
			Vitamin A (by UV)	
			Vitamin D3 (by HPLC)	
			Thiamine hydrochloride (by UV)	
			Riboflavin sodium phosphate (by UV)	
			Pyridoxine hydrochloride (by UV)	
			Cyanocobalamin (by Microbiological assay)	
			D-Panthenol (by UV)	
			Niacinamide (by UV)	
			L-Lysine hydrochloride (by UV)	
			Identification of colour	
			Weight per ml	
			Microbial Examination	
			Total aerobic count	
			Total fungal count	
			E. coli	
105	791	Intravenous Fat Emulsion 20% w/v (PL/TG Ratio 0.06) 250ml	Description	
			Extractable volume	
			pH	
			Density	
			Globule Size (A) By Microscopre	
			Globule Size (A) By Master Size	
			Potential Impurities	
			(A) Peroxide Value (By Titration)	
			(B) Free Fatty Acid (By HPLC)	
			Becterial endotoxins	
			Assay	
			Long Chain Triglycerides (BY HPLC)	
			Medium Chain Triglycerides (BY HPLC)	
			Glycerol (BY Titration)	
			Egg Lecithin (BY UV)	
			Sterility	
106	792	Tab. Pyridostigmine USP 60 mg (Each Tablet contains Pyridostigmine USP 60 mg)	**Pyridostigmine Tablets IP**	
			Description	
			Identification A (by UV)	
			Identification B (by TLC)	
			Identification C (by Chemical)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Disintegration test	
			Contents of Packaged Dosage Forms	
			Assay: (by UV)	
107	793	Inj. Caffeine Citrate USP 20mg/ml (equivalent to 10 mg caffeine base/ml) 3ml Size	Description	
			Identification A (by HPLC)	
			Identification B (by Chemical)	
			Identification C (by Chemical)	
			Colour and Clarity of solution	
			pH	
			Organic Impurities (By HPLC)	
			Becterial endotoxins	
			Particulate matter (by Particle counter)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Volume in container	
			Assay: (by HPLC)	
			Sterility	
108	794	Inj. Amino Acid 10% 100ml Size	Description	
			pH	
			Assay of Amino acid	
			Particulate matter (by Particle counter)	
			Extinction E	
			Sterility	
			Becterial endotoxins	
			Microbial Examination:	
109	795	Cap. Vitamin E 400 mg	**Vitamin E Capsules USP**	
			Description	
			Identification A	
			Identification B (Optical rotation)	
			Identification C (by GLC)	
			Average net content	
			Uniformity of dosage units (weight variation)	
			Disintegration test	
			Assay: (by GLC)	
110	796	Inj.Poractant Alpha80mg/ml in Pack of 1.5ml		
111	NE15	Misoprostol Tablet 600mg	Description	
			Identification A (by HPLC)	
			Average weight	
			Uniformity of content (by HPLC)	
			Contents of Packaged Dosage Forms	
			Disintegration time	
			Assay: (by HPLC)	
112	NE16	Dual Rapid Test Kit for HIV and Syphilis	**NIB**	
113	NE17	MTP (Medical Termination of pregnancy Drug Kit(Combipack of 1Tablet Mifeprestone 200mg and 4 tablet of misoprostol 200mcg	**Mifeprestone Tablets**	
			Description	
			Identification A (by HPLC)	
			Identification B (by UV)	
			Average weight	
			Uniformity of weight	
			Dissolution (by UV)	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
			Misoprostol Tablets	
			Description	
			Identification A (by HPLC)	
			Average weight	
			Uniformity of content (by HPLC)	
			Contents of Packaged Dosage Forms	
			Disintegration time	
			Assay: (by HPLC)	
114	NE18	Kanamycin Injection 500mg IP	**For solution**	
			Description	
			Identification (by TLC)	
			pH	
			Kanamycin B (by TLC)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Particulate matter	
			Extractable volume	
			Bacterial endotoxins	
			Assay: (by microbiological)	
			Sterility	
			For powder for injection	
			Description	
			Identification (by TLC)	
			pH	
			Kanamycin B (by TLC)	
			Average net content	
			Uniformity of weight	
			Clarity of solution test a and b	
			Particulate matter	
			Bacterial endotoxins	
			Assay: (by microbiological)	
			Sterility	
115	NE19	Kanamycin Injection 1000mg IP	**For solution**	
			Description	
			Identification (by TLC)	
			pH	
			Kanamycin B (by TLC)	
			Particulate matter	
			Extractable volume	
			Bacterial endotoxins	
			Assay: (by microbiological)	
			Sterility	
			For powder for injection	
			Description	
			Identification (by TLC)	
			pH	
			Kanamycin B (by TLC)	
			Average net content	
			Uniformity of weight	
			Clarity of solution test a and b	
			Particulate matter	
			Bacterial endotoxins	
			Assay: (by microbiological)	
			Sterility	
116	NE20	Levofloxacin Tablet 500mg IP	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
			Identification of colours	
117	NE21	Cycloserine Capsule 250mg IP	Description	
			Identification A	
			Identification B (by HPLC)	
			Average net content	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Condensation products (by UV)	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Loss on drying	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
118	NE22	Ethionamide Tablets 125mg IP	Description	
			Identification A (by IR)	
			Identification B (by HPLC)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
119	NE23	Ethionamide Tablets 250mg IP	Description	
			Identification A (by IR)	
			Identification B (by HPLC)	
			Average weight	
			Uniformity of weight	
			Related substances (by HPLC)	
			Dissolution (by UV)	
			Contents of Packaged Dosage Forms	
			Assay: (by HPLC)	
120	NE24	Capreomycin Injection 500mg	**For powder for injection**	
			Description	
			Identification A (by UV)	
			Identification B (by UV)	
			Appearance of solution	
			pH	
			Capreomycin I content (by HPLC)	
			Average net content	
			Uniformity of weight	
			Clarity of solution test a and b	
			Particulate matter	
			Bacterial endotoxins	
			Loss on drying	
			Assay: (by microbiological)	
			Sterility	
121	NE25	Moxifloxacin Tablets 400mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by UV)	
122	NE26	Clofazimine Capsules 100mg IP	Description	
			Identification A (by UV)	
			Identification B	
			Average net content	
			Uniformity of weight	
			Related substances (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: (by UV)	
123	NE28	Clarithromycin Tablets 500mg IP	Description	
			Identification (by HPLC)	
			Average weight	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Uniformity of weight	
			Dissolution (by HPLC)	
			Related substances (by HPLC)	
			Loss on drying	
			Contents of Packaged Dosage Forms	
			Assay: (by UV)	
124	NE29	Amoxycillin 875 mg + Calvulanic Acid 125 mg Tablets IP	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Water	
			Uniformity of content: Clavulanic acid (by HPLC)	
			Dissolution of	
			Amoxycillin (by HPLC)	
			Clavulanic acid (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay:	
			Amoxycillin (by HPLC)	
			Clavulanic acid (by HPLC)	
125	NE30	Pryidoxine Tablets 100mg IP	Description	
			Identification A (by UV)	
			Identification B (Chemical)	
			Average weight	
			Related substances (by TLC)	
			Uniformity of weight	
			Disintegration Time	
			Contents of Packaged Dosage Forms	
			Assay: (by UV)	
126	NE31	Hand Rub	Description	
			Identification (by GLC)	
			Identification (by chemical)	
			Filled Volume	
			Weight per ml	
			Assay:	
			2-propanol (by GLC)	
			1-propanol (by GLC)	
			Ethyl-hexadecyl-dimethyl,	
			ammonium ethyl sulfate	
			Microbial Examination:	
			Total aerobic count	
			Total yeast/Molds count	
			P aeruginosa	
			S aureus	
127	NE32	Ribociclib Tablets 200mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: Ribociclib succinate equivalent to Ribociclib succinate (by HPLC)	
128	NE33	Nilotinib Capsules 150mg	Description	
			Identification (by HPLC)	
			Average weight	

S. No.	Code No.	Name of Drug	Tests to be performed	Test parameters proposed to be carried out by bidder
1.	2.	3.	4.	5.
			Uniformity of weight	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: Nilotinib hydrochloride monohydrate equivalent to Nilotinib (by HPLC)	
129	NE34	Nilotinib 200mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: Nilotinib hydrochloride monohydrate equivalent to Nilotinib (by HPLC)	
130	NE35	Pazopanib 200mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: Pazopanib hydrochloride equivalent to Pazopanib (by HPLC)	
131	NE36	Pazopanib 400mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: Pazopanib hydrochloride equivalent to Pazopanib (by HPLC)	
132	NE37	Eltrombopag 50mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: Eltrombopag olamine equivalent to Eltrombopag (by HPLC)	
133	NE38	Eltrombopag 25mg	Description	
			Identification (by HPLC)	
			Average weight	
			Uniformity of weight	
			Dissolution (by HPLC)	
			Contents of Packaged Dosage Forms	
			Assay: Eltrombopag olamine equivalent to Eltrombopag (by HPLC)	

ANNEXURE –VIII
Ref: Clause no. 3 (p)

To fill up the remark column of the enclosed Performa to access the existing facilities of your laboratories

A - General requirements and premises

S.N.	Details of the requirement	Remark
1	For Laboratory management a qualified individual known as quality manager or technical manager is appointment.	
2	The Laboratory is designed, contracted and maintained to prevent entry of insects and rodents besides cross contaminations ;	
3	Interior surface (wall, floor, and ceilings) are smooth and free from cracks, and permit easy cleaning and disinfection ;	
4	Adequate provision for space and equipment for carrying out necessary test is provided & also unities like water, power and gas ;	
5	Air ventilations system is provide to ensure dust free environments	
6	The laboratories provided with adequate lighting and ventilation, air conditioning to maintain satisfactory temperature and relative humidity	
7	The faculties of drainage system and to prevent water logging in the laboratory	
8	Tables tops is made of with acid, alkali and solvent resistant material	
9	Adequate space with proper storage conditions in the laboratory shall be provided for keeping Reference and working standards	
10	The air circulation is maintained in the area where sterility test is carried out as per Schedule M.	

B- Personal & Equipment

S.N.	Details of the requirement	Remark
1	Staff in the laboratory shall possess necessary qualification, proper training and shall have Adequate, experience for the assigned duties.	
2	A training record of all the personal shall be maintained.	
3	Head of the laboratory must be high professional standing with experience in drug analysis and laboratories management	
4	The analytical instrument shall be housed in the dust-free environment and with controlled conditions of temperature and humidity	
5	A progress register for non functional equipments and action for procurement of spares and accessories, monitoring there of, shall be maintained	
6	A standard operating procedure for preventive maintenance of machine or equipment or apparatus shall be prepared by the laboratory	
7	Equipments such as burette, pipettes, volumetric flasks, weight boxes, thermometers etc. shall be thoroughly checked for accuracy for calibration before acceptance of use	
8	Equipments, instruments giving anomalous results or defective must be labeled as out of order	
9	Autoclaves must meet the requirements described for operations, safety and validation procedures	
10	Work involving the evolution of harmful and obnoxious vapors shall be carried out in a fume cupboard	

Chemicals and Reagents, Good housekeeping and safety

S.N.	Details of the requirement	Remark
1	All reagents and solutions in the laboratory shall be property identified with a label.	
2	A standardization register shall be maintained, with its raw date and SOP for preparation and standardization on stock solutions, standard solutions and volumetric solutions.	
3	Containers of stock solutions and of standard solutions shall bear the details.	
4	The storage and handling of chemicals and reagents shall be done in a manner considering the physicochemical properties substances and the hazard involved in their use.	
5	General and specific written down instructions for safety shall be circulated to each staff member.	
6	SOP for safety, house-keeping and loss prevention.	
7	Drinking, eating and smoking shall not be permitted in the laboratories.	
8	Staff must wear laboratory coats or other protective clothing including gloves and face masks and eye protection wherever required	
9	The laboratories shall have adequate firs aid kit and fire fighting equipments.	
10	Operators carrying out sterility tests shall wear sterilized garments including headgear, face masks and shoes.	
11	The staff must be educated in the first aid techniques, emergency care and use of antidotes.	
12	Safety rules in handling cylinders of compressed gases must be observed and staff must be familiar with relevant colors identification codes ;	
13	Protective Precautions - 1- water showered 2- Rubber suction bulbs must be used on manual and siphons ; 3- Warnings, precautions and written Instructions violent, uncontrollable or reactions. 4- Appropriate facilities for the collection, storage and disposal of wasters. 5- Safe disposal of corrosive or dangerous products by neutralization or deactivation. 6- Safety precautions to be adopted while handling potassium cyanide and bromide ; 7- SOP for handing, collection, disposal of chemical and biological wastes.	

Maintenance, calibration, and validation of equipment & Reference materials : Microbiological Cultures :

S.N.	Details of the requirement	Remark
1	All equipments, instruments and other devices used in the laboratory shall use appropriate methods and procedures for all tests or calibrations and they shall be regularly Calibrated and validated.	
2	For most of the equipments and instruments, SOP for calibration and calibration schedule be the laboratory and a logbook shall also be prepared by each laboratory for proper documentation of calibrations results.	

3	Reference material shall be traceable to agency authorized by Government of India or any other International body.	
4	The laboratory shall prepare working standard by comparing with the reference standards and shall be routinely checked for their purity.	
5	Whenever, any new reference material is received by the laboratory following details are to be written - a- Source of supply ; b- Code number of the reference material ; c- Date of receipt ; d- Batch number or identification number of the supplying agency ; e- Details like assay value, water content or information provided ; f- Storage condition of the material ; g- Date of expiry, if any and date of manufacturing if possible.	
6	SOP for maintenance of microbial culture and sub-culture must be prepared by the laboratories ;	

Quality system : & internal quality audits, management review :

S.N.	Details of the requirement	Remark
1	The measurements and calibrations shall fully conform to the compendia requirements and the method demonstrably based on validation protocols are followed.	
2	Remedial action o the observations by internal and external audits are taken appropriately	
3	Documented quality policy for the organization.	
4	Internal audits are done to assure the integrity of the analysis ad such audits shall be conducted periodically	
5	Each activity is audited at least once in a year.	
6	The quality manager shall maintain all the records of the analysis being conducted which includes test system, the type of analysis , date on which analysis is done	
7	Review yearly 1- Report or input 2- Matter arising from previous reviews ; 3- Report of external audits, if any ; 4- Surveillance report, if any ; 5- Result of proficiency testing ; 6- Complaints or feedback received from users 7- Details of in-house quality control checks ; 8- Need of amendment of the quality system and documentation ; 9- Introduction training of new staff.	

Standard operating Procedures

S.N.	Details of the requirement	Remark
1	Shall be written in a chronological order listing different steps leading to an analysis of drugs or calibration of an instruments ;	
2	Shall have SOP manuals and have periodic Review.	
3	Standard Operation Procedures for the followings are required (i) Sample handling and accountability ; (ii) Receipt identification, storage, mixing and method sampling of the test	

S.N.	Details of the requirement	Remark
	and control articles ; (iii) Record keeping, reporting, storage and retrieval of data ; (iv) Coding of different studies, handling of data including use of computerized data system : (v) Operation of technical audit personnel in performing and reporting audits, inspections and final report reviews ; (vi) Routing inspection of cleaning maintenance, testing, calibration and standardization of instruments ; (vii) Action to be taken in respect of equipment failure ; (viii) Analytical data methods (ix) Health and safety protection ; (x) Date handling and storage retrieval ; (xi) Health and safety protection ; (xii) Animal room preparations ; (xiii) Animal care ; (xiv) Storage and maintenance of microbial cultures ; (xv) Maintenance of sterility room (i.e. constant maintenance and monitoring of Aseptic condition room) ; (xvi) Use and storage of reference standards ; (xvii) Procurement of stores and equipment ; (xviii) Monitoring of testing of samples ; (xix) Method of retention of unexpended samples, their location, maintenance and disposal ; (xx) Document control ; (xxi) Redressal of technical complaints ; (xxii) House- keeping (xxiii) Corrective and preventive action ; (xxv) Calibration manual. (xxvi) Training manual.	
4	Protocols and specification archive :- List of all the pharmacopeias a file on patent and proprietary medicines (non-Pharmacopeia) test methods to specification prepared and validated by the manufacturer. The test methods shall be submitted to the concerned Drug Control Authority.	
5	Raw data - Date integrity and security shall be maintained Original entry must be saved and the system shall trail for all data.	
6	Storage and archival ; The residual sample shall be retained in proper storage condition for a period of one year after the final report.	
7	The laboratory must establish and maintain procedures for the identification collection, indexing, retrieval, storage, maintenance, and Disposal of all quality documents.	
8	All the raw date, documentation, SOP, protocols and final reports are the be retained and there shall be archives of orderly storage and expeditious retrieval of all raw data, documentation, protocols, interim and final report.	
9	The condition under which the original documents are stored must ensure	

S.N.	Details of the requirement	Remark
	their security and confidentiality.	
10	Raw data on thermal paper might fad away with time ; therefore, a photocopy of the thermal paper shall be retained in the archive.	

Above mentioned information correct as per our record and if found incorrect, RMSC may take action against our firm and reject our bid.

Signature:
Name of the Lab:
Date:
Official Seal: