

Ref. No.: F.02(242)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-09/2018/696 Dated :- 07.05.2018

**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](mailto:rmsc@nic.in),  
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**E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING  
LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS  
(Ending on 30.06.2020)**



!! सर्वे सन्तु निरामया:!!

<b>LAST DATE OF SUBMISSION OF ONLINE BIDS</b>	<b>18.06.2018 &amp; 6.00 PM</b>
<b>DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS</b>	<b>19.06.2018 and 11.30 AM</b>

**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: rmisc@nic.in**

**Ref. No.:** F.02(242)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-09/2018/696 Dated :- 07.05.2018

**Notice Inviting E-Bids**

E-bids are invited up to 6.00 PM of **18.06.2018** from approved Drugs Testing Laboratories situated in the state of Gujarat, Rajasthan, Madhya Pradesh, Haryana, Maharashtra, Himachal Pradesh, Uttar Pradesh, Punjab, Uttarakhand, Karnataka, Andhra Pradesh, Telangana, Daman and NCR of Delhi for analysis of Drugs. (Ending on **30.06.2020**) 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://www.dipronline.org), <http://eproc.rajasthan.gov.in>, [www.rmisc.nic.in](http://www.rmisc.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.rmisc.nic.in](http://www.rmisc.nic.in), [sppp.raj.nic.in](http://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 :- MSC1819SLRC00019)**

**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 30.06.2020)**

<b>Bid Reference</b>	:	F.02(242)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-09/2018/696	Dated :- 07.05.2018
<b>Pre- bid conference</b>	:	<b>23.05.2018 at 11.00 A.M.</b> (RMSC meeting Hall)	
<b>Date and time for downloading bid document</b>	:	<b>17.05.2018 from 2.00 PM</b>	
<b>Last date and time of submission of online bids</b>	:	<b>18.06.2018 at 6.00 PM</b>	
<b>Date and time of opening of Online technical bids</b>	:	<b>19.06.2018 at 11.30 AM</b>	
<b>Cost of the Bid Document</b>	:	<b>Rs. 2000/-</b>	
<b>RISL Processing Fees</b>	:	<b>Rs. 1000/-</b>	
<b>EMD</b>	:	<b>Rs. 20000/-</b>	

**RAJASTHAN MEDICAL SERVICES CORPORATION LTD.  
RAJASTHAN**

**E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING  
LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS  
(Ending on 30.06.2020)**

*“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 18.06.2018 By The Rajasthan Medical Services Corporation Ltd, For The Empanelment Of Analytical Testing Laboratories For The Test And Analysis Of DRUGS (Ending on 30.06.2020) 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 **18.06.2018** 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 **18.06.2018** 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, foods and other 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 the state of Gujarat, Rajasthan, Madhya Pradesh, Haryana, Maharashtra, Himachal Pradesh, Uttar Pradesh, Punjab, Uttarakhand, Karnataka, Andhra Pradesh, Telangana, Daman and NCR of Delhi
- (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 **or** 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 Lakhs** for past preceding three years (2014-15, 2015-16 and 2016-17).
- (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.
- (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.
- 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) or 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 registration for service tax.
- g. Non- Conviction Certificate by the State Licensing Authority/ competent authority.
- h. Annual turnover statement for 3 year i.e. 2014-2015, 2015-2016 and 2016-17 certified by the practising Chartered Accountant.
- i. Copies of the Balance Sheet and Profit and Loss Account for three years i.e. 2014-2015, 2015-2016 and 2016-17 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. Bidders 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 coated separately at last entry of BOQ. Any type of uncalled for clarification on prices and or rebates shall not be accepted.**

**It is further clarified that if a bidder does not fill the IGST, CGST, SGST column, or does not fill any other column, than the bid shall be treated as uncompleted and liable to be rejected prima-facie.**

#### **5 OPENING OF TECHNICAL BID AND FINANCIAL BID EVALUATION**

- 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 **18.06.2018** or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSC by 6.00 PM on **18.06.2018** 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 test 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 **30.06.2020**. This may be further extended for a further period of three months with mutual consent.
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. 1000 /-** (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. PERFORMANCE SECURITY**

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. PAYMENT 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. COMPLIANCE WITH THE CODE OF INTEGRITY AND NO CONFLICT OF INTEREST:**

Any person participating in an 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 hired) by the Procuring Entity as engineer-in-charge/ consultant for the contract.

#### **18. JURISDICTION**

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**

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

Bank Copy

**punjab national bank**

DIST. NO.

Branch

Institute Name

Institute ID

Rajasthan Medical Services Corporation, Jaipur

**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 *		
<b>Total</b>		

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹	0	0	0	0	-	0	0
Commission ₹	0	0	0	0	-	0	0
Total amount ₹					-		

Amount (in words): ₹

Name of the Depositor \_\_\_\_\_

Signature \_\_\_\_\_

Address for communication \_\_\_\_\_

Acknowledgement

*[Signature]*

Cashier/Officer

Customer Copy

**punjab national bank**

DIST. NO.

Branch

Institute Name

Institute ID

Rajasthan Medical Services Corporation, Jaipur

**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 *		
<b>Total</b>		

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹	0	0	0	0	-	0	0
Commission ₹	0	0	0	0	-	0	0
Total amount ₹					-		

Amount (in words): ₹

Name of the Depositor \_\_\_\_\_

Signature \_\_\_\_\_

Address for communication \_\_\_\_\_

Acknowledgement

*[Signature]*

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.

<b>S.No.</b>	<b>Years</b>	<b>Turnover in Lakhs</b>	
1	2014-15		
2	2015-16		
3	2016-17		
<b>Total</b>		<b>Rs.</b>	<b>Lakhs</b>
<b>Average turnover per annual</b>		<b>Rs.</b>	<b>Lakhs</b>

Date:

Seal:

Signature of Auditor/  
Chartered Accountant  
(Name in Capital)

**PROFORMA FOR PERFORMANCE STATEMENT**  
**(for a period of last 3 years)**

Name of the Laboratory : \_\_\_\_\_

Address: \_\_\_\_\_

Types of Samples Analysed	No. of Samples Analysed during <b>(2014-15, 2015-16 and 2016-17)</b> or <b>(2015-16, 2016-17 and 2017-18)</b>
---------------------------	--

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 :

**PERSONNEL IN QC DEPARTMENT**

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 :

Name of the Lab :

Office Seal :

**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:

**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)**

**LIST OF REFERENCES SAMPLES ALONG WITH THEIR DATE OF  
PROCUREMENT 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 30.06.2020) 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(242)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-09/2018/696 Dated 07.05.2018

6. For the empanelment of analytical testing laboratories for the test and analysis of DRUGS (Ending on 30.06.2020) 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. I/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 .....

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

**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)**

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
1.	2	Bupivacaine Hydrochloride in Dextrose Injection USP Each ml contains Bupivacaine Hydrochloride 5.0 mg Dextrose 80.0 mg.		
2.	4	Bupivacaine Injection IP 0.5%		
3.	5	Drotaverine Hydrochloride Injection 40 mg/2 ml		
4.	6	Halothane BP 250 ml		
5.	7	Isoflurane USP		
6.	8	Ketamine Injection IP 50 mg/ml		
7.	9	Lignocaine Ointment 5%		
8.	10	Lignocaine and Adrenaline Inj. IP Each ml. Contains :- Lignocaine Hydrochloride IP 20 mg. Adrenaline IP 0.01 mg		
9.	11	Lignocaine and Dextrose Injection IP Each ml contains Lignocaine 50 mg and Dextrose (monohydrate) 75 mg		
10.	12	Lignocaine Gel IP 2%		
11.	13	Lignocaine injection IP 2%		
12.	14	Propofol Injection IP/BP/USP 10 mg/ ml		
13.	15	Thiopentone Injection IP 0.5 gm		
14.	19	Diclofenac Sodium Injection IP 25 mg/ ml (IM/IV use)		
15.	20	Diclofenac Gastro Resistant Tablets IP 50 mg (Enteric Coated)		
16.	21	Fentanyl Citrate Injection IP 50 mcg /ml		
17.	22	Ibuprofen and Paracetamol Tablets Ibuprofen 400 mg+Paracetamol 325mg		
18.	23	Ibuprofen Tablets IP 200 mg (Coated)		
19.	24	Ibuprofen Tablets IP 400 mg (Coated)		
20.	25	Morphine Sulphate Injection IP 10mg/ml		
21.	26	Paracetamol Drops [Paediatric Paracetamol Oral Suspension IP] (Each ml contains Paracetamol 150 mg)		
22.	27	Paracetamol Syrup IP 125 mg/5ml (40% Sugar base with strawberry flavour and carmoisine colour)		
23.	28	Paracetamol Tablets IP 500 mg		
24.	29	Paracetamol Inj. 150mg/ml		
25.	30	Pentazocine Injection IP 30mg/ml (IM/IV Use)		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
26.	32	Tramadol Capsules IP 50 mg		
27.	33	Tramadol Injection 50 mg/ ml		
28.	34	Adrenaline Injection IP 1mg/ml (IM/IV use)		
29.	35	Betamethasone Tablets IP 0.5mg		
30.	37	Chlorpheniramine Maleate Tablets IP 4 mg		
31.	39	Dexamethasone Injection IP 8 mg/2ml		
32.	40	Dexamethasone Tablets IP 0.5mg		
33.	42	Hydrocortisone Sod. Succinate Injection IP 100 mg base / vial (IM/IV use)		
34.	43	Hydroxyzine Tablets IP 25 mg		
35.	44	Methyl Prednisolone Sodium Succinate for Injection USP 500 mg		
36.	45	Pheniramine Injection IP 22.75mg/ml		
37.	47	Prednisolone Tablets IP 5 mg		
38.	48	Promethazine Syrup IP 5mg/5ml		
39.	49	Promethazine Injection IP 25mg/ml		
40.	50	Promethazine Tablets IP 25 mg		
41.	51	Naloxone Injection IP 0.4mg/ ml		
42.	52	Pralidoxime Chloride Injection IP 500mg		
43.	53	Carbamazepine Tablets IP 200 mg (Film Coated)		
44.	54	Carbamazepine Tablets IP 100 mg (Film Coated)		
45.	56	Phenobarbitone Tablets IP 30 mg		
46.	57	Phenytoin Injection 50mg/ml		
47.	58	Phenytoin Oral suspension IP 25mg/ml		
48.	59	Phenytoin Tablets IP 100 mg (Film Coated)		
49.	60	Sodium Valproate IP Injection 100 mg/ ml		
50.	61	Sodium Valproate Gastro resistant Tablet IP 200 mg		
51.	62	Acyclovir Oral Suspension IP 400mg/5ml		
52.	63	Acyclovir Tablets IP 200 mg		
53.	64	Acyclovir Tablets IP 800 mg		
54.	65	Albendazole Oral suspension IP 400 mg/10ml		
55.	66A	Albendazole Tablets IP 400 mg (Colour: Sunset Yellow FCF in suitable Flavoured Base)		
56.	67	Amikacin Injection IP 100 mg		
57.	68	Amikacin Injection IP 500 mg		
58.	69	Amoxycillin and Cloxacillin Capsules 250mg + 250 mg		
59.	70	Amoxycillin and Potassium Clavulanate Tablets IP 500 mg + 125 mg		
60.	71	Amoxycillin Capsules IP 250mg		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
61.	72	Amoxicillin Capsules IP 500mg		
62.	73	Amoxicillin Dispersible Tablets IP 125mg		
63.	74	Amphotericin B Injection IP 50 mg		
64.	75	Ampicillin Injection IP 500 mg		
65.	78A	Azithromycin Tablets 100 mg Dispersible Tablets		
66.	79A	Azithromycin Tablets IP 250 mg		
67.	80A	Azithromycin Tab IP 500 mg		
68.	81	Benzathine Benzylpenicillin Inj IP 12 lac units		
69.	82	Benzathine Benzylpenicillin Inj IP 6 lac units		
70.	84	Cefixime Tablets IP 100 mg		
71.	85	Cefixime Tablets IP 200 mg		
72.	86	Cefoperazone and Sulbactam for Injection Cefoperazone Sodium eq. to Cefoperazone 1 g and Sulbactam Sodium eq. to Sulbactam 0.5 g (IM/ IV use)		
73.	87	Cefotaxime Injection 1gm		
74.	88	Cefotaxime Injection IP 250 mg		
75.	89	Ceftazidime Injection IP 1 gm		
76.	90	Ceftazidime Injection IP 250 mg		
77.	91	Ceftazidime Injection IP 500 mg		
78.	93	Ceftriaxone Injection IP 1gm /vial		
79.	94	Ceftriaxone Injection IP 250 mg/ vial		
80.	95	Ceftriaxone Injection IP 500mg/vial		
81.	96	Cephalexin Capsules IP 250 mg		
82.	97	Cephalexin Capsules IP 500 mg		
83.	98	Chloroquine Phosphate Injection IP 40mg/ml		
84.	99	Chloroquine Phosphate Tab. IP 250mg (Eq to 155 mg of Chloroquine base) (Film Coated)		
85.	100A	Chloroquine Phosphate Suspension IP 50 mg/5ml		
86.	101	Ciprofloxacin Injection IP 200mg/100ml		
87.	102	Ciprofloxacin Tablets IP 250 mg (Film Coated)		
88.	103	Ciprofloxacin Tablets IP 500 mg (Film Coated)		
89.	104	Clotrimazole Cream IP 2% w/w		
90.	105	Clotrimazole Vaginal Tablets IP 500 mg		
91.	106	Compound Benzoic Acid Ointment IP [Benzoic Acid 6%+ Salicylic Acid 3%]		
92.	107	Co-trimoxazole Oral suspension IP Each 5 ml contains Trimethoprim 40 mg and Sulphamethoxazole 200 mg		
93.	108	Co-trimoxazole Tablets IP Trimethoprim 40 mg and Sulphamethoxazole 200 mg		
94.	110	Diethylcarbamazine Tablets IP 100 mg		



<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
95.	111	Doxycycline Capsules IP 100 mg		
96.	114A	Fluconazole Tab. IP 150mg		
97.	116	Gentamicin Injection IP 80mg/2ml (IM/ IV use)		
98.	117	Griseofulvin Tablet IP 125 mg		
99.	118	Itraconazole Capsules 100 mg		
100.	119	Meropenem Injection IP 500 mg		
101.	120	Metronidazole Injection IP 500 mg/100ml		
102.	121	Metronidazole Benzoate Oral Suspension IP 100 mg of base/5ml		
103.	122	Metronidazole Tablets IP 200 mg (Film Coated)		
104.	123	Metronidazole Tablets IP 400 mg (Film Coated)		
105.	124	Norfloxacin Tablets IP 400 mg (Film Coated)		
106.	125	Ofloxacin Tablets IP 200 mg		
107.	128	Primaquine Tablets IP 2.5 mg		
108.	129	Primaquine Tablets IP 7.5 mg		
109.	131	Quinine Dihydrochloride Injection IP 300 mg/ ml		
110.	132	Quinine sulphate Tablets IP 300mg (Film Coated)		
111.	133	Azathioprine Tablets IP 50 mg		
112.	134	Bleomycin Injection IP 15 mg (Bleomycin Sulphate Injection 15 units)		
113.	136	Chlorambucil Tablets IP 5 mg		
114.	137	Cisplatin Injection IP/BP 50 mg/50ml		
115.	138	Cyclophosphamide Injection IP 200 mg		
116.	139	Cyclophosphamide Injection IP 500 mg		
117.	141	Cytarabine Injection BP 500mg		
118.	142	Danazol Capsules IP 50 mg		
119.	143	Daunorubicin Injection IP 20 mg		
120.	144	Doxorubicin Injection IP 50 mg/ 25 ml		
121.	146	Etoposide Injection IP 100 mg		
122.	147	Flunarizine Tablets 5 mg		
123.	148	Fluorouracil Injection IP 250 mg/ 5ml		
124.	149	L-Asparaginase Injection 10000 IU		
125.	150	Leucovorin Calcium Injection IP/Calcium Folate Injection IP 10 mg /ml		
126.	151	Melphalan Tablets IP 5 mg		
127.	152	Mercaptopurine Tablets IP 50 mg		
128.	153	Methotrexate Injection IP 50 mg/ 2 ml		
129.	154	Methotrexate Tablets IP 2.5 mg		
130.	155	Paclitaxel Injection IP 260 mg		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
131.	156	Paclitaxel Injection IP 100 mg		
132.	157	Tamoxifen Tablets IP 10 mg		
133.	158	Vinblastine Injection IP 10mg		
134.	159	Vincristine Injection IP 1 mg (Vial) / Vincristine Injection USP 1 mg/ml (Amp)		
135.	160	Levodopa and Carbidopa Tablets IP [Levodopa 100mg + Carbidopa 10 mg]		
136.	161	Levodopa 250mg and Carbidopa 25 mg Tab IP		
137.	162	Trihexyphenidyl Hydrochloride Tablets IP 2 mg		
138.	163	Acenocoumarol Tablets IP 2 mg (Nicoumalone Tab IP)		
139.	165	Deferasirox Tablets 100 mg		
140.	166	Deferasirox Tablets 500 mg		
141.	167	Deferiprone Capsules 250 mg		
142.	168	Deferiprone Capsules 500 mg		
143.	169	Desferrioxamine Injection IP 500 mg / Vial (For I.M. Inj and I.V., S.C. Infusion)		
144.	171	Dried Human Anti haemophilic Fraction IP (Dried Factor VIII Fraction IP) 250 IU/ Vial (IV use)		
145.	172	Enoxaparin Sodium Injection IP 60 mg		
146.	173	Ethamsylate Injection 250 mg/ 2ml (IM/IV)		
147.	174	Heparin Sodium Injection IP 5000 IU/ml [IM/IV Use]		
148.	175	Human Albumin Solution IP 20%		
149.	176	Rh-Erythropoetin Injection 10000 IU		
150.	177	rh-Erythropoetin Injection 2000IU		
151.	179	Rh-Erythropoetin Injection 4000 IU		
152.	180	Vitamin K Injection Each ml Contains Menadione Sodium Bisulphite 10 mg Equivalent to 5.2 mg of Menadione. (Aqueous Solution)		
153.	181	Amiodarone Tablets IP 100 mg		
154.	182	Amiodarone Tablets IP 200 mg		
155.	183	Amiodarone Hydrochloride Injection 50 mg/ml		
156.	184	Amlodipine Tablets IP 2.5 mg		
157.	185	Amlodipine Tablets IP 5 mg		
158.	186	Atenolol Tablets IP 50 mg		
159.	187	Atorvastatin Tablets IP 10 mg		
160.	188	Clopidogrel Tablets IP 75 mg		
161.	189	Digoxin Injection IP 0.25 mg/ml		
162.	190	Digoxin Tablets IP 0.25 mg.		
163.	191	Diltiazem Tabs IP 30 mg (Film Coated)		
164.	192	Dobutamine Injection IP/BP 250 mg (Vial) /		

S.N	Code No.	Name of item with specification	Test proposed to be carried out	Remark
		Dobutamine Injection USP 250 mg/5ml (Amp)		
165.	193	Dopamine Hydrochloride Injection 40 mg/ml		
166.	194	Enalapril Maleate Tablets IP 5mg		
167.	195	Enalapril Maleate Tablets IP 2.5mg		
168.	197	Isosorbide dinitrate Tablets IP 5 mg		
169.	198	Isosorbide mononitrate Tabs IP 20 mg		
170.	199	Lisinopril Tablets IP 5 mg		
171.	200	Losartan Tablets IP 50 mg		
172.	201	Magnesium Sulphate Injection IP 500mg/ml (50% w/v)		
173.	202	Methyldopa Tablets IP 250mg Film Coated		
174.	203	Nifedipine capsules IP 5mg		
175.	204	Nifedipine Tablets IP 10 mg (Sustained Release)		
176.	205	Nitroglycerin Injection 5 mg/ ml		
177.	207	Propranolol Tablets IP 40 mg		
178.	209	Streptokinase Injection IP 15 lac units		
179.	211	Verapamil Tablets IP 40 mg (Film Coated)		
180.	213	Acyclovir Cream 5%		
181.	215A	Cetrimide Cream IP		
182.	216A	Fusidic Acid Cream IP 2%		
183.	217	Glycerin IP		
184.	218	Liquid Paraffin IP		
185.	219	Ointment containing : Lidocaine IP 3%, Zinc oxide IP 5% , Hydrocortisone IP 0.25%, Allantoin IP 0.5%		
186.	220	Miconazole Nitrate Cream IP 2%		
187.	221	Povidone Iodine Ointment 5%		
188.	222	Povidone Iodine solution IP 5%		
189.	223	Powder Neomycin Bacitracin with Sulphacetamide (Neomycin 5mg, Bacitracin 250 units, Sulphacetamide 60 mg)		
190.	224	Silver Sulphadiazine cream IP 1%		
191.	225	Anti A Blood Grouping Serum IP (Anti A Monoclonal Serum)		
192.	226	Anti B Blood Grouping Serum IP (Anti B Monoclonal Serum)		
193.	227	Anti D (Rh) Blood Grouping Serum IP / Anti D Blood Grouping Serum IP		
194.	232	Diatrizoate Meglumine and Diatrizoate Sodium Inj USP 60% (iodine conc = 292 mg/ml)		
195.	233	Diatrizoate Meglumine and Diatrizoate Sodium Inj USP 76% w/v (iodine conc =370 mg/ml)		
196.	235	Gadodiamide Inj. 0.5 mmol/ml Vial		

S.N	Code No.	Name of item with specification	Test proposed to be carried out	Remark
197.	241	Tropicamide Eye Drops IP 1%		
198.	242	VDRL Antigen (with +ve and -ve control) / RPR slide Kit		
199.	244	Compound Benzoin Tincture IP		
200.	245	Formaldehyde Solution (34.5% - 38%)		
201.	246	Gentian Violet Topical Solution USP 1%		
202.	247	Gluteraldehyde solution 2 %		
203.	248	Hydrogen Peroxide Solution IP 6% (20 Vol)		
204.	249	Lysol (Cresol with Soap Solution) IP Cresol 50% + Soap 50%		
205.	250	Povidone Iodine Scrub Solution / cleansing solution 7.5% w/v Povidone Iodine (suitable for hand wash)		
206.	252	Surgical Spirit IP/BP		
207.	253	Acetazolamide Tablets IP 250mg		
208.	254	Frusemide Tablets IP 40 mg.		
209.	255	Furosemide Injection IP 10mg/ml (IM & IV use)		
210.	256	Hydrochlorothiazide Tablets IP 12.5 mg		
211.	257A	Mannitol Injection IP 20% w/v		
212.	258	Spironolactone Tablets IP 25 mg		
213.	259	Torsamide Tablets 10 mg		
214.	260A	Antacid Tablets Formula: Each chewable tablet contains Magnesium Trisilicate 250mg, Dried Aluminium Hydroxide Gel 120mg, Peppermint oil		
215.	261A	Antacid Liquid Each 5ml contains Dried Aluminium Hydroxide Gel 250 mg, Magnesium Hydroxide 250mg, Activated polydimethyl siloxane 50mg		
216.	262	Bisacodyl Tablets IP 5 mg		
217.	263	Dicyclomine Tablets IP 10 mg		
218.	264	Dicyclomine Injection IP 10 mg /ml		
219.	265	Dicyclomine Hydrochloride Oral Solution IP 10mg /5ml		
220.	266	Domperidone Suspension IP 5mg/5ml		
221.	267	Domperidone Tablets IP 10 mg		
222.	268	Hyoscine Butylbromide Injection IP 20 mg/ ml		
223.	269	Loperamide Tablets IP 2 mg		
224.	270	Metoclopramide Injection IP 10mg/2ml		
225.	271	Metoclopramide Tablets IP 10 mg		
226.	272	Omeprazole Capsules IP 20 mg		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
227.	273	Ondansetron Injection IP 2mg/ml		
228.	274	ORS Powder IP		
229.	275	Pantoprazole Injection 40 mg		
230.	276	Ranitidine HCL Injection IP 50mg/2ml		
231.	277	Ranitidine Tablets IP 150mg (Film coated)		
232.	278	Sodium Phosphates Enema BP Each 100ml contains Sodium Dihydrogen phosphate Dihydrate 10%, Disodium Hydrogen Phosphate Dodecahydrate 8%		
233.	279	Biphasic Isophane Insulin Injection IP (30% Soluble Insulin & 70% Isophane Insulin) Inj 40 IU/ml (r-DNA origin)		
234.	280	Carbimazole Tabs IP 5 mg (Film Coated)		
235.	281	Carboprost Tromethamine Injection Each ml contains Carboprost 0.25mg/ml		
236.	282	Clomifene Tablets IP 25 mg		
237.	283	Clomiphene Tablets IP 50 mg		
238.	284	Conjugated Estrogen Tabs USP 0.625 mg.		
239.	285	Dinoprostone Cream/Gel 0.5 mg Dinoprostone in syringe		
240.	286	Ethinylloestradiol Tabs IP 50 mcg		
241.	287	Glibenclamide Tablets IP 5 mg		
242.	288	Gliclazide Tablets IP 40 mg		
243.	289	Glimepiride Tablets IP 2 mg		
244.	290	Glimepiride Tablets IP 1 mg		
245.	291	Glipizide Tablets IP 5mg		
246.	293	Hydroxyprogesterone Injection IP 250mg/ ml		
247.	294	Isophane Insulin Injection IP 40 IU/ml		
248.	295	Metformin Tablets IP 500 mg. (Film Coated)		
249.	296	Norethisterone Tablets IP 5 mg		
250.	297	Pioglitazone Tablets IP 15 mg		
251.	298	Progesterone Injection IP 200 mg/ 2ml		
252.	300	Insulin Injection IP (Soluble Insulin / Neutral Insulin Injection) 40 IU/ ml. (r-DNA origin)		
253.	301	Thyroxine Sodium Tablets IP 100mcg		
254.	303	Human Anti D Immunoglobulin Injection 300mcg (I.M.use)		
255.	304	Human Anti D Immunoglobulin 150 mcg		
256.	305	Human Rabies Immunoglobulin Injection 150 IU/ ml		
257.	306	Rabies Vaccine Human (Cell Culture) IP (Intradermal) 2.5 IU		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
258.	307	Rabies Vaccine Human (Cell Culture) IP (Intramuscular) 2.5 IU/ dose		
259.	308	Snake Venum Anti Serum IP (Lyophilized) Polyvalent Anti Snake Venum, Serum Enzyme Refined. Contain purified equine globulins. 1 ml of serum neutralizes 0.6 mg of cobra venum, 0.45 mg of common krait (Bungarus) venum, 0.6 mg of Russell's Viper Venum and 0.45 mg of Saw-scaled Viper Venum.		
260.	309	Tetanus Immunoglobulin 250 IU/ Vial		
261.	310	Tetanus Vaccine (adsorbed) I.P.		
262.	311	Atracurium Injection 10 mg/ml		
263.	312	Glycopyrrolate Injection USP 0.2 mg/ml		
264.	313	Midazolam Injection IP 1 mg/ml		
265.	314	Neostigmine Injection IP 0.5 mg/ml		
266.	316	Neostigmine Tablets IP 15 mg		
267.	317	Succinylcholine Injection IP 50 mg/ml (IV use)		
268.	318	Valethamate Bromide Injection 8mg /ml		
269.	319	Atropine Eye Ointment IP 1%		
270.	320	Atropine Sulphate Ophthalmic Solution USP 1%		
271.	321	Chloramphenicol Eye Drops IP 0.5%		
272.	322	Ciprofloxacin Eye Drops 0.3% w/v		
273.	323	Ciprofloxacin Ophthalmic Ointment USP 0.3%		
274.	324	Hydroxypropylmethyl cellulose solution 20 mg/ ml		
275.	326	Pilocarpine Eye Drops IP 2%		
276.	330	Tobramycin and Dexamethasone Ophthalmic Suspension USP 0.3%+0.1%		
277.	331	Tobramycin Eye Drops 0.3%		
278.	332	Tobramycin Ophthalmic Ointment USP 0.3%		
279.	333	Isoxsuprine Injection IP 5 mg/ml		
280.	334	Isoxsuprine Tablets IP 20 mg		
281.	335	Methylergometrine Injection IP 0.2mg/ml		
282.	336	Methylergometrine Tablet IP 0.125 mg		
283.	337	Misoprostol Tablets IP 200 mcg		
284.	338	Oxytocin Injection IP 5 IU/ml		
285.	339	Alprazolam Tablets IP 0.25 mg		
286.	340	Alprazolam Tablets IP 0.5mg		
287.	341	Amitriptyline Tablets IP 25mg Film Coated		
288.	342	Chlordiazepoxide Tablets IP 10mg		
289.	343	Chlorpromazine Tablets IP 100 mg (Coated Tablet)		
290.	344	Chlorpromazine Tablets IP 25 mg (Sugar- Coated)		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
291.	345	Chlorpromazine Tabs IP 50 mg. (Coated Tablets)		
292.	346	Chlorpromazine Inj. IP 25mg/ml		
293.	349	Diazepam Injection IP 10mg/2ml (1M/IV use)		
294.	350	Diazepam Tablets IP 5 mg		
295.	351	Escitalopram Tablets IP 10 mg		
296.	352	Fluoxetine Capsules IP 20 mg		
297.	353	Haloperidol Injection IP 5 mg/ml		
298.	354	Haloperidol Tablets IP 1.5 mg		
299.	355	Haloperidol Tablets IP 5 mg		
300.	356	Imipramine Tablets IP 25 mg (Coated Tablets)		
301.	357	Imipramine Tablets IP 75 mg (Coated)		
302.	358	Lithium Carbonate Tablets IP 300 mg		
303.	359	Lorazepam Injection 2 mg/ml		
304.	360	Olanzapine Tablets IP 5 mg		
305.	361	Risperidone Tablets 2 mg		
306.	362	Risperidone Tablets 1 mg		
307.	363	Sertraline Tablets 50 mg		
308.	364	Trifluoperazine Tablets IP 5 mg (Coated)		
309.	365	Aminophylline Injection IP 25 mg/ml		
310.	366	Beclomethasone Inhalation IP 200 mcg/ dose		
311.	367	Budesonide Nebulizer Suspension 0.25mg/ ml		
312.	368	Cough Syrup Each 5ml contains Chlorpheniramine Maleate IP 3mg Ammonium Chloride 130mg, Sodium Citrate 65 mg, Menthol 0.5 mg, Syrup Q.S.		
313.	369	Ipratropium Bromide Nebulizer Solution 250 mcg/ ml		
314.	370	Salbutamol Tablets IP 4 mg		
315.	371	Salbutamol Inhalation 100 mcg /dose		
316.	372	Salbutamol Nebuliser Solution BP 5 mg/ml		
317.	373	Salbutamol Tablets IP 2 mg		
318.	374	Theophylline and Etofylline Injection (Anhydrous Theophylline 50.6mg + Etofylline 169.4 mg)		
319.	375	Theophylline and Etofylline Tablets (Theophylline IP 23mg + Etofylline IP 77 mg)		
320.	376	Theophylline Tablets 400 mg Sustained release/controlled release (Theophylline prolonged Release Tablets IP)		
321.	377	Compound Sodium Lactate inj. IP		
322.	378	Dextrose Injection IP 25 % w/v		
323.	379	Dextrose injection IP 10%		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
324.	380	Dextrose injection IP 5%		
325.	381	Multiple Electrolytes & Dextrose Injection Type I IP (Electrolyte 'P' Injection )		
326.	382	Multiple Electrolytes & Dextrose Injection Type III IP Electrolyte "M" Injection ( I.V.)		
327.	383	Potassium Chloride Injection 0.15 gm/ml		
328.	384	Potassium chloride Oral Solution U.S.P 500mg/ 5ml		
329.	385	Sodium Chloride and Dextrose Inj. I.P (0.9%+5%)		
330.	386	Sodium Chloride Injection IP		
331.	387	Ascorbic Acid Tablets IP 500 mg		
332.	388	Calcium Gluconate Injection IP 10% (IV use)		
333.	390	Ferrous Sulphate and Folic Acid Tab IP Each film coated Tab. Containing Dried Ferrous Sulphate IP-equivalent to 100mg Elemental Iron and Folic Acid IP 0.5mg		
334.	391	Ferrous Sulphate with Folic Acid Tab. (Paediatric) IP Each film coated Tab. Containing Dried Ferrous Sulphate IP- quivalent to 20mg Elemental Iron and Folic Acid IP 100 mcg.		
335.	392	Folic Acid Tablets IP 5 mg		
336.	393	Multivitamin Drops Each ml contains Vit-A -3000 IU, Vit-D3-300 IU, Vit-B1 -1mg, Riboflavine Phosphate Sodium -2mg, D-Panthenol -2.5mg, Niacinamide - 10mg, Pyridoxine HCL-1mg, Cyanocobalamin 1mcg, Lysine HCL 10mg		
337.	394	Multivitamin Tablets NFI Formula Sugar coated. Vit A 2500 IU, Vit B1-2mg, Vit- B6-0.5mg, Vit-C-50mg, Calcium Pantothenate-1mg, Vit-D3-200IU, Vit-B2 2 mg, Niacinamide-25mg, Folic Acid-0.2 mg		
338.	395	Vitamin B Complex Injection NFI		
339.	397	Vitamin – B complex tablet NFI(prophylactic) B1- 2mg, B2- 2mg, B6-0.5mg, Niacinamide 25mg, Calcium pantothenate 1mg (With appropriate overages)		
340.	398	Black Disinfectant Fluid (Phenyl) (As per Schedule "O" Grade – III		
341.	399	Concentrated Solution for Haemodialysis B.P Acetate concentrate in 10 Litre Cans.		
342.	401	Peritoneal Dialysis Solution IP		
343.	402	Sodium Bicarbonate Injection IP 7.5% w/v		
344.	404	Water for injection I.P.		
345.	405	Polygeline 3.5% Solution with electrolytes for I.V. Infusion		
346.	406	Factor – IX Concentrate (Purified) 500-600 I.U.(Human Coagulation Factor IX)		



<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
347.	407	Anti-Inhibitor coagulation Complex (Human Plasma Protein with a Factor VIII Inhibitor Bypassing Activity of 500 IU per Vial)		
348.	408	Rabies Antiserum IP (Equine) 300 units per ml [contains equine anti-rabies immunoglobulin fragments](I.M./SC use)		
349.	409	Vitamin A Paediatric oral solution IP Vitamin A concentrate oil IP Each ml contains vitamin A 100000 IU		
350.	410	Labetalol Tablets IP 100mg		
351.	411	Labetalol Hydrochloride Injection IP 20mg/4ml		
352.	412	Ampicillin Capsules IP 500 mg		
353.	413	Nitrofurantoin Tablets IP 100mg		
354.	414	Hyoscine Butylbromide Tablets IP 10mg		
355.	415	Drotaverine Tablets IP 40 mg		
356.	416	Hydroxyethyl Starch (130/0.4) 6% w/v with Sodium Chloride 0.9% w/v Intravenous Infusion		
357.	417	Cloxacillin sodium Injection IP 500 mg		
358.	418	Betamethasone Sodium Phosphate injection IP 4mg/ml		
359.	419	Vecuronium Bromide for Injection 4 mg (Freeze Dried)		
360.	420	Phenobarbitone Injection IP 200mg/ml		
361.	421	Flurbiprofen Sodium Ophthalmic Solution USP 0.03% w/v / Flurbiprofen Eye Drops IP 0.03% w/v		
362.	423	Hyaluronidase Injection IP Each vial contains Hyaluronidase IP 1500 I.U.		
363.	424	Lidocaine Hydrochloride Topical Solution USP 4%		
364.	425	Fluconazole Eye Drops 0.3%		
365.	427	Cephalexin Oral Suspension IP (Cephalexin Dry Syrup IP) 125 mg/ 5 ml		
366.	428	Ofloxacin oral Suspension IP 50mg/ 5ml		
367.	430	Tinidazole Tablets IP 300 mg (Film Coated)		
368.	431	Tinidazole Tablets IP 500 mg (Film Coated)		
369.	432	Salbutamol Syrup IP 2mg/ 5ml		
370.	433	Ranitidine Tablets IP 300 mg (Film coated)		
371.	436	Indomethacin Capsules IP 25 mg		
372.	437	Diclofenac Prolonged Release Tablete IP 100mg		
373.	438	Dicyclomine Hydrochloride and Activated Dimethicone suspension. Each ml contains: Dicyclomine Hydrochloride 10mg, Activated Dimethicone 40mg		
374.	439A	Dicyclomine and Paracetamol Tablets Dicyclomine Hydrochloride 20 mg + Paracetamol 325 mg Tablets		
375.	440	Dextromethorphan Hydrobromide Syrup IP 13.5mg / 5ml		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
376.	441	Calcium & Vitamin D3 Suspension (Each 5 ml contains Calcium Carbonate equivalent to elemental Calcium 250 mg, Vitamin D3 - 125 IU )		
377.	442	Saline Nasal Solution (Drops / Spray) (Sodium chloride 0.65%)		
378.	443	Clotrimazole mouth paint (Clotrimazole 1% w/v)		
379.	444	Aspirin Gastro resistant Tablets IP Each enteric coated tablet contains Acetyl Salicylic Acid 75 mg		
380.	445	Beclomethasone, Neomycin and Clotrimazole Cream (Beclomethasone dipropionate 0.025%, Neomycin sulphate 0.5% Clotrimazole 1%)		
381.	446	Gamma Benzene Hexachloride Lotion 1% (Lindane lotion USP) (Lindane Application BP)		
382.	447	Chlorhexidine Gluconate Solution 5%		
383.	448	Iron and Folic Acid Suspension.		
384.	449	Surgical Spirit IP/BP		
385.	450	Povidone Iodine Solution IP 5%		
386.	451	Metformin Hydrochloride Sustained Release Tablets IP 1000 mg		
387.	452	Glipizide and Metformin Hydrochloride Tablets USP (Glipizide 5mg, Metformin Hydrochloride 500 mg)		
388.	453	Glibenclamide and Metformin Hydrochloride (SR) Tablets [Glibenclamide 5mg, Metformin Hydrochloride 500 mg (Sustained Release)]		
389.	454	Metformin Hydrochloride (Sustained Release) and Glimperiride Tablets {Metformin Hydrochloride (Sustained Release) 500 mg, Glimipiride 1 mg}		
390.	455	Metformin Hydrochloride (Sustained Release) and Glimepiride Tablets {Metformin Hydrochloride (Sustained Release) 500 mg, Glimepiride 2 mg}		
391.	456	Glimperiride, Pioglitazone and Metformin Hydrochloride (Sustained Release) Tablets Each Tablet contains Glimepiride 2mg, Pioglitazone 15mg, Metformin Hydrochloride(Sustained release) 500 mg		
392.	457	Amlodipine and Enalapril Maleate Tablet (Amlodipine Besilate equivalent to Amlodipine 5mg, Enalapril maleate 5mg)		
393.	458	Losarton Potassium & Amlodipine tablets IP (Losarton Potassium 50 mg, Amlodipine Besilate eq. to Amlodipine 5mg)		
394.	459	Losarton Potassium & Hydrochlorothiazide Tablets IP (Losarton Potassium 50 mg, Hydrochlorothiazide Tablets 12.5mg)		
395.	460	Amlodipine and Lisinopril Tablets [Amlodipine Besilate equivalent to Amlodipine 5 mg, Lisinopril eq.		

S.N	Code No.	Name of item with specification	Test proposed to be carried out	Remark
		to lisinopril (anhydrous) 5mg]		
396.	461	Amlodipine and Atenolol Tablets [Amlodipine Besilate equivalent to Amlodipine 5 mg, Atenolol 50mg]		
397.	462	Atenolol Tablets IP 25 mg		
398.	463	Enalapril Maleate Tablets IP 10 mg		
399.	464	Hydrochlorthiazide Tablets IP 25 mg		
400.	465	Lisinopril Tablets IP 10 mg		
401.	466	Lisinopril Tablets IP 2.5 mg		
402.	467	Losartan Tablets IP 25 mg		
403.	468	Piperacillin and Tazobactam for Injection USP 4 gm + 500 mg		
404.	469	Prednisolone Tablets IP 10 mg		
405.	470	Prednisolone Tablets 20 mg		
406.	471	Torsemide Injection 10 mg/ml		
407.	472	Zinc Sulphate Dispersible Tablets IP Elemental Zinc 10 mg		
408.	473	Amoxycillin Oral Suspension IP (Dry Syrup) 125 mg/ 5 ml		
409.	474	Carbamazepine Oral Suspension USP 100 mg/5ml		
410.	475	Cefpodoxime Dispersible Tablets 50 mg		
411.	476	Cephalexin Tablets 125 mg (Dispersible Tablets)		
412.	477	Ibuprofen Oral Suspension BP/USP 100 mg/ 5 ml		
413.	478	Metoclopramide Hydrochloride Syrup IP 5 mg/ 5ml		
414.	479	Sodium Valproate Oral Solution IP 200 mg / 5 ml		
415.	480	Diphtheria Antitoxin 10000 IU		
416.	481	Meropenem Injection IP 1 gm		
417.	482	Iohexol USP (Solution for Injection) Non Ionic contrast medium in Sterile aqueous solution 300 mg Iodine/ml.		
418.	483	Diclofenac Sodium and Paracetamol Tablets Diclofenac Sodium 50 mg + Paracetamol 325 mg		
419.	484	Timolol Eye Drops IP 0.5% w/v		
420.	485	Homatropine Eye Drops IP 2 %		
421.	486	Travoprost Eye Drops IP 0.004%		
422.	487	Brimonidine Tartrate and Timolol Maleate Eye Drops 0.15% + 0.5%		
423.	488	Iron Sucrose Injection USP/BP 20mg/ml (For IV Use) Each ml contain: Ferric hydroxide in complex with Sucrose equivalent to elemental Iron 20 mg		
424.	491	Sevoflurane		
425.	492	Aceclofenac and Paracetamol Tablets Aceclofenac 100 mg and Paracetamol 325 mg		
426.	493	Diclofenac Gel: Diclofenac Diethylamine 1.16%,		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
		Methyl salicylate 10%, Linseed oil 3% and Menthol 5%		
427.	495	Etoricoxib Tablets IP 120 mg		
428.	496	Mefenamic Acid Tablets BP 500 mg		
429.	497	Anticold syrup Each 5 ml contains Phenylephrine Hydrochloride 2.5mg , Chlorpheniramine maleate 1 mg, and Paracetamol 125 mg		
430.	498	Cetirizine, Phenylephrine & Paracetamol Tablets Cetirizine 5 mg, Phenylephrine 10 mg & Paracetamol 325 mg		
431.	499	Cetirizine syrup IP 5 mg/ 5ml		
432.	500	Acetylcystine Solution USP /BP (Injection ) 200 mg/ml		
433.	502	Acyclovir Intravenous Infusion IP 250 mg		
434.	503	Acyclovir Intravenous Infusion IP 500 mg		
435.	504	Amikacin Injection IP 250 mg		
436.	505	Amoxicillin and Potassium Clavulante Injection IP 600 mg		
437.	506	Amoxicillin and Potassium Clavulante Injection IP 1.2 g		
438.	507	Amoxicillin and Potassium Clavulante Oral Suspension IP 200 mg + 28.5 mg per 5 ml		
439.	508A	Artesunate Injection 60 mg (I.M./I.V. Use) Each Combo Pack contains Artesunate Injection 60 mg Vial, Sodium Bicarbonate Injection IP 5% w/v (1 ml ampoule), Sodium chloride Injection IP 0.9% w/v (5 ml ampoule)		
440.	509	Aztreonam Injection USP 500 mg		
441.	510	Cefepime Injection IP 500 mg		
442.	511	Cefixime Oral Suspension IP 25 mg/ ml (Paediatric Drops)		
443.	512	Cefuroxime Axetil Tablets IP 250 mg		
444.	513	Clindamycin Capsules IP 150 mg		
445.	514	Clindamycin Capsules IP 300 mg		
446.	515	Levofloxacin Tablets IP 250 mg		
447.	516	Linezolid Tablets IP 600 mg		
448.	517	Linezolid Injection 200 mg/ 100 ml		
449.	518	Mefloquine Tablets IP 250 mg		
450.	519	Metronidazole & Norfloxacin suspension 100 + 100 mg per 5 ml		
451.	520	Ofloxacin and Ornidazole Tablets (Ofloxacin 200 mg and Ornidazole 500 mg)		
452.	521	Ofloxacin Infusion IP 200mg/ 100 ml (in NaCl Inj)		
453.	523	Vancomycin for Intravenous Infusion IP 500 mg		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
454.	524	Vancomycin for Intravenous Infusion IP 1 gm		
455.	525	Alpha Interferon Injection (Interferon Alpha-2 concentrated Solution IP) 3 million unit		
456.	526	Carboplatin Injection 150 mg		
457.	527	Carboplatin Injection 450 mg		
458.	528	Cisplatin Injection IP 10 mg/ 10 ml		
459.	529	Dacarbazine Injection 500 mg USP/ BP		
460.	530	Filgrastim Injection (Granulocyte Colony Stimulation Factor) 300 mcg [SC/IV use]		
461.	531	Gemcitabine for Injection 200 mg		
462.	532	Gemcitabine for Injection 1 gm		
463.	533	Ifosfamide Injection USP/ BP 1 gm		
464.	534	Imatinib Tablets 400 mg		
465.	536	Methotrexate Tablets IP 10 mg		
466.	537	Mitomycine Injection IP 10 mg / Mitomycine for Injection USP 10 mg		
467.	538	Oxaliplatin Injection USP 50 mg		
468.	540	Bromocriptine Tablets IP 2.5 mg		
469.	541	Betahistine Tablets IP 8 mg		
470.	542	Betahistine Tablets IP 16 mg		
471.	543	Cinnarizine Tablets IP 25 mg		
472.	544	Cinnarizine Tablets IP 75 mg		
473.	545	Tranexamic Acid Tablets IP/BP 500 mg		
474.	546	Warfarin Sodium Tablets IP 5 mg		
475.	547	Adenosine Injection 6 mg/ 2 ml		
476.	548	Atorvastatin Tablets IP 40 mg		
477.	549	Clopidogrel and Aspirin Tablets Clopidogrel 75 mg and Aspirin 75 mg		
478.	550	Fenofibrate Capsules / Tablet IP 200 mg		
479.	551	Isoprenaline Injection IP 2 mg/ml		
480.	552	Metoprolol Tablets IP 25 mg		
481.	553	Metoprolol Succinate Extended Release Tablets USP 50 mg		
482.	554	Noradrenaline Injection IP 2 mg/ml		
483.	555	Prazosin Tablets (Extended Release) 2.5 mg		
484.	556	Telmisartan Tablets IP 40 mg		
485.	557	Urokinase Injection 5 Lac Unit (Lyophilized)		
486.	558	Betamethasone Dipropionate Cream IP 0.05%		
487.	559	Betamethasone Lotion IP 0.05%		
488.	560	Clindamycin Phosphate Gel USP 1%		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
489.	561	Clobetasol Propionate Cream 0.05%		
490.	564	Glycerin IP		
491.	565	Ketoconazole Cream 2%		
492.	568	Permethrin Lotion 5%		
493.	569	Permethrin Cream 5%		
494.	570	Tretinoin Cream USP 0.025%		
495.	571	Povidone Iodine Ointment USP 5%		
496.	572	Povidone Iodine Solution IP 10%		
497.	573	Silver Sulphadiazine Cream IP 1%		
498.	574	Spirolactone Tablets IP 50 mg		
499.	575	Finasteride Tablets IP 5 mg		
500.	576	Tamsulosin HCl Tablets/Capsule 0.4 mg		
501.	577	Terazosin Tablets IP 1 mg		
502.	578	Terazosin Tablets USP 2 mg		
503.	579	Flavoxate Tablets IP/BP 200 mg (Coated Tablet)		
504.	580	Chlorhexidine Mouthwash IP/BP 0.2%		
505.	581	Dental Gel: Choline salicylate 8.7%, Benzalkonium Chloride 0.01%, Lignocaine HCl 2% (flavoured gel base)		
506.	582	Tooth Gel: Sodium Monofluorophosphate 0.7% and Potassium Nitrate 5% (in flavoured base)		
507.	583	Gum Paint containing Tannic acid 2%, Cetrimide 0.1%, Zinc Chloride 1%		
508.	584	Metronidazole 1% and Chlorhexidine gluconate 0.25% Gel		
509.	585	Ciprofloxacin 0.3% and Dexamethasone 0.1% Ear Drops Ciprofloxacin and Dexamethasone Otic Suspension USP		
510.	586	Clotrimazole 1% with Beclomethasone Dipropionate 0.025% Ear Drops		
511.	588	Neomycin, Polymixin B and Hydrocortisone Ear Drops (Neomycin sulphate 3400 IU, Polymixin B Sulphate 10000 IU, and Hydrocortisone 10 mg per ml) Neomycin and Polymixin B Sulfate and Hydrocortisone Otic Solution USP		
512.	589	Ceruminolytic Drops (Wax dissolving ear drops): Paradichlorobenzene 2%, Benzocaine 2.7%, Chlorbutol 5%, Turpentine oil 15%		
513.	590	Domeperidone Oral Drops 10 mg/ ml		
514.	591	Drotaverine & Mefenamic Acid Tablets Drotaverine 80 mg and Mefenamic Acid 250 mg		
515.	592	Lactic Acid Bacillus Tablets 60 million spores		
516.	593	Lactulose solution USP/ BP 10 gm/ 15 ml or 3.35gm/5		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
		ml		
517.	594	Liquid Paraffin IP		
518.	595	Ondansetron Orally Disintegrating Tablets IP 4 mg		
519.	596	Pantoprazole 40 mg and Domperidone 30 mg SR Capsules Pantopazole as enteric coated pellets, and Domperidone as sustained release pellets		
520.	597	Ursodeoxycholic Acid Tablets 300 mg		
521.	598	Allopurinol Tablets IP 100 mg		
522.	599	Hydroxychloroquine Sulphate Tablets 200 mg		
523.	600	Leflunomide Tablets IP/USP 10 mg (Film coated)		
524.	601	Leflunomide Tablets IP/USP 20 mg (Film coated)		
525.	602	Sulfasalazine Delayed Release Tablets USP/ Gastroresistant Sulfasalazine Tablets BP 500 mg		
526.	603	Gliclazide and Metformin Tablets Gliclazide 80 mg and Metformin Hydrochloride 500 mg		
527.	604	Glucagon for Injection USP 1 mg		
528.	605	Medroxyprogesterone acetate Tablets IP 10 mg		
529.	607	Thyroxine Tablets IP 50 mcg		
530.	608	Octreotide Injection 50 mcg/ ml		
531.	610	Chlorzoxazone, Diclofenac Sodium & Paracetamol Tablets (Chlorzoxazone 250 mg, Diclofenac Sodium 50 mg & Paracetamol 325 mg)		
532.	612	Betaxolol Eye Drops 0.5%		
533.	613	Carboxymethylcellulose Eye Drops 0.5%		
534.	614	Phenylephrine Hydrochloride Ophthalmic Solution USP/ Phenylephrine Eye Drops BP 5%		
535.	615	Mifepristone Tablets IP 200 mg		
536.	616	Formoterol Fumerate and Budesonide Powder for Inhalation IP 6 mcg + 200 mcg		
537.	617	Budesonide Powder for Inhalation 200 mcg		
538.	618	Ipratropium Powder for Inhalation IP 40 mcg		
539.	619	Terbutaline Tablets IP 2.5 mg		
540.	620	Xylometazoline Nasal Drops IP 0.1 %		
541.	621	Sodium Chloride Injection IP		
542.	622	Calcium Carbonate & vitamin D3 Tablets / Calcium with Vitamin D Tablets USP/ Calcium and Colecalciferol Tablets BP (Elemental Calcium 500 mg, Vitamin D3- 250 IU)		
543.	623	Cholecalciferol granules 60, 000 IU/ gm		
544.	624	Mecobalamin Injection 500 mcg/ ml		
545.	626	Pyridoxine Tablets IP 10 mg		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
546.	627	Pyridoxine Tablets IP 40 mg		
547.	629	Thiamine Tablets IP 100 mg		
548.	630	Calcitriol Capsules IP 0.25 mcg		
549.	631	Alendronate Sodium Tablets USP / BP 35 mg		
550.	632	Mannitol with Glycerin Injection 10% +10% w/v (For Intravenous Infusion)		
551.	633	Normal Human Intravenous Immunoglobulin 5 gm/ 100 ml		
552.	634	Pregabalin Capsules IP 75 mg		
553.	635	Surfactant for intratrecheal instillation (natural bovine lung surfactant)		
554.	636	Ramipril Tablet IP 2.5 mg		
555.	638	Neostigmine Injection IP 2.5 mg/5 ml		
556.	639	Oseltamivir Capsule IP 75 mg [Each Capsule contains Oseltamivir Phosphate equivalent to Oseltamivir 75 mg]		
557.	640	Oseltamivir Capsule IP 45 mg [Each Capsule contains Oseltamivir Phosphate equivalent to Oseltamivir 45 mg]		
558.	641	Oseltamivir Capsule IP 30 mg [Each Capsule contains Oseltamivir Phosphate equivalent to Oseltamivir 30 mg]		
559.	642	Oseltamivir Phosphate for Oral Suspension IP 12 mg/ml. [Each ml contains 12 mg Oseltamivir base after reconstitution]		
560.	642A	Oseltamivir Phosphate For Oral Suspension IP 12 Mg/MI (Each MI Contains 12 Mg Oseltamivir Base After Reconstitution)		
561.	644	Vitamin K1 (Phytomenadione ) Injection 1 mg/0.5 ml Ampoule (aqueous Preparation)Each Pack contains:(i) One 0.5 ml Ampoule of Vitamin K 1(ii) One 1 ml disposable syringe with one 26 gaze needle		
562.	645	ACT Containing 3 tablet of Artesunate (each tablet of artesunate 25mg strength)and 1 tablet of Sulphadoxine Pyremethamine (250mg+12.5mg)		
563.	646	ACT Containing 3 tablets of Artesunate(50mg each) and 1 tablet of Sulphadoxine Pyremethamine(500+25)mg		
564.	647	ACT Containing 3 tablets of Artesunate(100mg each) and 1 tablet of Sulphadoxine Pyremethamine(750+37.5)mg		
565.	648	ACT Containing 3 tablets of Artesunate 150mg and 2 tablets of Sulphadoxine Pyremethamine(500mg+25mg)		
566.	649	ACT Containing 3 tablets of Artesunate(each 200 mg) and 2 tablets of Sulphadoxine Pyremethamine(750+37.5)mg each or 3 tablets		



<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
		Sulphadoxine Pyremethamine(500+25)mg each		
567.	650	Glyceryl Trinitrate Tablets 2.6 mg Controlled Release tablets		
568.	651	Artemether and Leumefantrin Tablet (80 mg + 480 mg)		
569.	652	Methyl Cobalmine 500 mcg Tab.		
570.	653	Methyl Cobalmine 1500 mcg Tab		
571.	654	Atropine Sulphate Inj. IP 0.6 mg/ml (SC/IM/IV use)		
572.	655	Fentanyl Citrate Inj. IP 50 mcg/ml		
573.	656	Naproxen Tablet IP 500 mg		
574.	657	Naproxen Tablet IP 250 mg		
575.	658	Etoricoxib Tablets IP 90 mg		
576.	659	Levocetizine Tablet 5 mg		
577.	660	Montelukast (10 mg) +Levocetizine (5mg) Tab.		
578.	661	Sodium Valproate Tablet (Gastro Resistant) IP 500 mg		
579.	662	Clobazam Tablet/Capsule 5 mg		
580.	663	Clobazam Tablet/Capsule 10 mg		
581.	664	Levetiracetam 500 mg Tab		
582.	665	Levetiracetam 100 mg/ml oral solution		
583.	666	Levetiracetam Injection 500 mg/5ml		
584.	667	Gabapentin Tablet/Capsule 100 mg		
585.	668	Gabapentin Tab / Cap 300 mg		
586.	669	Co-trimoxazole Tablets [Trimethoprim 160 mg+ Sulphamethoxazole 800 mg]		
587.	670	Coal tar 6% & Salicylic Acid 3% Ointment		
588.	671	Calamine Lotion IP		
589.	672	Iohexol USP (Solution for injection) Non Ionic contrast medium in Sterile aqueous solution 350 mg Iodine/ml.		
590.	673	Diagnostic Stick for Multiple use strip (sugar, ketone, Albumin)		
591.	674	Quetiapine Tab IP 50 mg		
592.	675	Quetiapine Tab IP 25 mg		
593.	676	Vitamin D3 Oral Solution 60000 IU		
594.	677	Cyclosporin Capsules USP 50 mg		
595.	678	Clonazepam Tablets IP 0.5 mg		
596.	679	Aspirin Tablets IP (Gastro-resistant) 150 mg		
597.	680	Insulin Glargine 100 IU/ml		
598.	681	Insulin Glargine 100 IU/ml		
599.	682	Teneligliptin Tablet 20 mg		
600.	683	Inj. Aztreonam 1 gm		

<b>S.N</b>	<b>Code No.</b>	<b>Name of item with specification</b>	<b>Test proposed to be carried out</b>	<b>Remark</b>
601.	684	Framycetin Sulphate Cream 1%		
602.	685	Framycetin Sulphate Cream 1%		
603.	686	Artemether and Leumefantrin Tablet (40 mg + 240 mg)		
604.	687	Concentrated Solution for Haemodialysis B.P Sodium Hydrogen carbonate concentrate in 10 Litre Cans.		
605.	688	Dried Human Anti haemophlic Fraction IP (Dried Factor VIII Fraction IP) 500 IU/ Vial (IV use)		
606.	689	Dried Human Anti haemophlic Fraction IP (Dried Factor VIII Fraction IP) 1000 IU/ Vial (IV use)		
607.	690	Recombinant Coagulation Factor VIIa 1 mg		
608.	691	Recombinant Coagulation Factor VIIa 2 mg		
609.	448W	Iron And Folic Acid Syrup IP		
610.	489P	Iron And Folic Acid Tablets		
611.	490W	Iron And Folic Acid Tablets (Wifs Junior)		
612.	NE1	Buprenorphine 2mg + Naloxone 0.5 mg Tablet		
613.	NE2	Misoprostol Tablets 200 mcg		
614.	NE3	Treponemal-Specific Rapid (Point-of- Care) Diagnostic Test for Syphilis		
615.	NE4	Whole Blood Finger Prick Test kit for HIV (Rapid)		
616.	NE6	Multiple Urine Analysis Strip		
617.	NE7	Injection rTPA (Recombinant tissue Plasminogen Activator) for stroke management 20 mg		
618.	NE8	Injection rTPA (Recombinant tissue Plasminogen Activator) for stroke management 50 mg		
619.	NE9	Levothyroxine Sodium Tablet IP 25 mcg		
620.	NE10	Levothyroxine Sodium Tablet 50 mcg		
621.	NE11	Post exposure prophylaxis drugs for HIV- Drug Combinati on : Tenofovir 300 mg+ Lamivudine 300 mg + Efavirenz 600 mg		
622.	NE12	Anti - Oxidants Capsule (Beta Carotene – 10 mg, Vit - E 25mg, Vit - C 100 mg, Copper 1.5 mg, Manganese 1.5 mg, Zinc 7.5 mg, Selenium 150 microgram		

**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	

S.N.	Details of the requirement	Remark
	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 first 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 ;	

S.N.	Details of the requirement	Remark
	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 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.	

S.N.	Details of the requirement	Remark
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 - Data 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 data, documentation, SOP, protocols and final reports are to 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 their security and confidentiality.	
10	Raw data on thermal paper might fade 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: