Ref. No.: F.02(350)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-07/2022/866 Dated :30.03.2022

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: edprmsc@nic.in

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS (Ending on 30.06.2024)

!! सर्वे सन्तु निरामयाः!!

LAST DATE OF SUBMISSION OF ONLINE BIDS	**20.04.2022 & 6.00 PM**
DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS	**21.04.2022 & 11.00 AM**

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
(A Govt. of Rajasthan Undertaking)
Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India
Phone No: 0141-2228066, 2228064 Website: www.rmsc.health.rajasthan.gov.in
CIN:U24232RJ2011SGC035067 E-mail : edprmsc@nic.in

Ref. No.: F.02(350)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-07/2022/866 Dated :30.03.2022

Notice Inviting E-Bids

E-bids are invited up to 6.00 PM of 20.04.2022 from approved Drugs Testing Laboratories situated in India for analysis of Drugs. (Ending on **30.06.2024**) Details may be seen in the Bidding Documents at our office or at the website of State Public procurement Portal http://sppp.raj.nic.in, www.dipronline.org, http://eproc.rajasthan.gov.in. , www.rmsc.nic.in and may be downloaded from there.

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

(UBN : MSC2122GLRC00157

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 30.06.2024)

Bid Reference	**:**	F.02(350)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-07/2022/ 866 Dated :30.03.2022
Pre- bid conference	**:**	**05.04.2022 at 11.00 A.M.**
Date and time for downloading bid document	**:**	**30.03.2022 from 02.00 PM**
Last date and time of submission of online bids	**:**	**20.04.2022 at 6.00 PM**
Date and time of opening of Online technical bids	**:**	**21.04.2022 at 11.00 PM**
Cost of the Bid Document	**:**	**Rs. 2000/-**
RISL Processing Fees	**:**	**Rs. 1000/-**
Bid Security	**:**	**Rs. 20000/-**

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
RAJASTHAN

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS (Ending on 30.06.2024)

"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 20.04.2022 By The Rajasthan Medical Services Corporation Ltd, For The Empanelment Of Analytical Testing Laboratories For The Test And Analysis Of DRUGS (Ending on **30.06.2024**) 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 20.04.2022 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 20.04.2022 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 Bid security the Bids will be rejected and will not be opened.**

2. **<u>Eligibility Criteria for Empanelment :-</u>**

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

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

(3) The laboratory should have an average annual turnover of **not** less than **Rs. 50 Lakh** for past preceding three years **(2017-18, 2018-19 & 2019-20 or 2018-19 , 2019-20 & 2020-21)**

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

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

(i) Bid rejection

(ii) Bid Security forfeiture

(iii) Agreement rejection

(iv) Performance Security forfeiture

(v) Blacklisting

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

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

3 **TECHNICAL BID**

The Bidder must furnish the following in technical bid.

a. Bidders are allowed the option to quote for anyone item or more items as mentioned in bid (list of medicines proposed to be testing at Annexure-VII). The bidder has to mentioned type of test for each item to be carried out by him, the filled up annexure VII to be submitted with technical bid.

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

b. The bidders shall submit/upload scanned copy of all the challans in Technical Bid deposited for Bid fees, RISL processing fee and Earnest Money, in case deposited in any branch of PNB throughout country. The required EMD / Tender fees/ RISL fee may be in form of physical D.D./ BC along with letter. D.D. / bankers cheque shall be in favour of M.D. RMSCL (tender fees and EMD), MD, RISL (tender procession fees).

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

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

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

f. Attested copy of certificate of GST registration.

g. GST return 01.09.2021 to 31.12.2021

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

i. Annual turnover statement for 3 year i.e. **(**2017-18, 2018-19 & 2019-20 or 2018-19, 2019-20 & 2020-21**)** certified by the practicing Chartered Accountant.

j. Copies of the Balance Sheet and Profit and Loss Account for three years i.e. **(**2017-18, 2018-19 & 2019-20 or 2018-19, 2019-20 & 2020-21**)** duly audited or certified by the practicing Chartered Accountant.

k. 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".

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

m. Details of Laboratory in Annexure – VI.

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

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

p. 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.

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

4 PRICE BID:

The price bid will also be known as financial document and every bidder will be required to submit its price in excel format attached to the bid document (BOQ). **BOQ template must not be modified/ replaced by the bidder and the same should be uploaded after filling the relevant columns, else the bidder is liable to be rejected for this bid. Bidders are allowed to enter the bidder name and values only**. **The bidder should quote rate for the complete tests as applicable to the item. The rate for sterility test for sterile products should also be quoted separately at last entry of BOQ. Any type of uncalled for clarification on prices and or rebates shall not be accepted.**

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

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

6 BID SECURITY

The Bid Security 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 20.04.2022 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSC by 6.00 PM on 20.04.2022 Earnest Money Deposit in any other form will not be accepted

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

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

7 GENERAL CONDITIONS

1. The details of the Drugs, to be analysed shall be given in **Annexure VII**.
2. The Bidder should quote the rates for complete analysis of each product and name of test to be performed, methodology to be used for each test should be mentioned in **Annexure-VII**. **However wherever rates for individual test are demanded, they should be furnished accordingly in BOQ. Wherever tests are prescribed and their name and methodology for testing are not stated, such lab will not be considered responsive testing for such item.**
3. The rates quoted should be exclusive of taxes.
4. The rates quoted and accepted will be binding on the Bidder for the stipulated period and on no account any revision will be entertained till the completion of the BID period.
5. Analytical Laboratory, which also has its manufacturing activity, if empanelled by RMSC, then Samples of its own manufacturing unit shall not be sent to its empanelled laboratory for testing.
6. The laboratory will not be permitted to outsource any test from other laboratory.

7. RMSCL shall have the right to cause the laboratory to be inspected by the members of its technical committee before opening of price bid and subsequently as and when considered appropriate and based on the finding, the

Bidder may be disqualified or de-empanelled, as the case may be.

8. Conditional tender will not be accepted and rejected immediately.

8. ACCEPTANCE OF BID

1. The Bid evaluation committee formed by Managing Director, Rajasthan Medical Services Corporation Ltd. will evaluate the Bid with reference to various criteria.
2. The Managing Director, Rajasthan Medical Services Corporation Limited reserves the right to accept or reject any BID for any one or more of the items Bided for, without assigning any reason.
3. The Managing Director, Rajasthan Medical Services Corporation Limited has the right to accept one or more bidders depending on the volume of analytical work.

9. AGREEMENT

1. **The agreement with empanelled laboratories will remain valid up to 30.06.2024. If Required period of contract can be extended upto 3 months same rate, terms and condition without any prior consent and shall be binding on approved bidder.**
2. RMSCL will issue letters of Intent (LOIs) to successful bidders and bidders who are empanelled will have to execute an agreement on a non-judicial stamp paper of value **Rs. 500 /-** (Stamp duty to be paid by the Bidder), in favour of Managing Director, Rajasthan Medical Services Corporation Limited Jaipur within 15 days from the date of receipt of the intimation to them informing that their BIDs have been accepted. The format of agreement will be issued by RMSCL.
3. The Bidder shall not, at any time, assign, sub-let or make over the contract or the benefit therefore or any part thereof to any person or persons whatsoever.
4. All notices or communication relating to, or arising out of this agreement or any of the terms thereof shall be considered duly served on or given to the Bidder if delivered to him or left at the premises, places of business or abode.

10. <u>PERFORMANCE SECURITY</u>

1. The successful Bidders shall be required to pay a Performance Security 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 A and should have S. no. , name of drug sample, code no., batch no., mfg. date, exp. date, description of tests, protocol of test specified & applied, findings & results obtained and should be signed by person-in-charge of testing. In case of Not of Standard Quality Reports the reports shall be release on Pink/Red colored paper for easy identification of NOSQ drugs.

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

2. All test reports of each batch of sample should be submitted to the RMSC in triplicate. In case of failure of a sample, the result should be communicated

immediately to the Executive Director (Q.C.) through phone / E-mail and the report should be sent along with protocol.

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

12. PAYM ENT PROVISIONS

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

13. PENALTIES

1. If the successful Bidder fails to execute the agreement and payment of security deposit within the time specified or withdraws the BID after intimation of the acceptance of the BID has been sent to or owing to any other reasons, he is unable to undertake the contract, the empanelment will be cancelled and the Earnest Money Deposit deposited by the Bidder shall stand forfeited in favour of the Rajasthan Medical Services Corporation Limited. Such Bidder(s) will also be liable for all damages sustained by the Rajasthan Medical Services Corporation Limited due to of breach of BID conditions. Such damages shall be assessed by the Managing Director, Rajasthan Medical Services Corporation Limited whose decision shall be final.
2. Non performance of any BID or empanelment conditions will disqualify a laboratory to participate in the BID for the period as decided by RMSCL.
3. To assess the correctness of the test results being given by the Empanelled laboratories, samples at random, would also be sent to the Government Analyst for testing and if any variation is found the result would be informed to empanelled laboratories. If there is any gross variation in the analytical reports furnished by the empanelled laboratories (either pass or fail) with Government Lab for 3 times in assay test and 4 times for any other specification, in a year, the empanelled laboratory shall be considered for blacklisting for a period as considered proper after following the due process.
4. 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.

5. 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.
6. In all matters pertaining to the BID, the decision of the Managing Director, Rajasthan Medical Services Corporation Limited shall be final and binding.
7. (i)If the laboratory requires an extension in time for submission of test report, on account of occurrence of any hindrance he shall apply in writing for extension on occurrence of hindrance but not after the stipulated date of ***furnishing the test report***.

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

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

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

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

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

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

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

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

14. CORRECTION OF ARITHMETIC ERRORS:

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

(i) If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price shall be corrected, unless in the opinion of the Procuring Entity there is an obvious misplacement of the decimal point in the unit price, in which case the total price as quoted shall govern and the unit price shall be corrected;

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

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

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

15. GRIEVANCE REDRESSAL DURING EMPANELMENT PROCESS:

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

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

i. Filling an appeal

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

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

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

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

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

iv. Appeal not to lie in certain cases

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

(a) Determination of need of empanelment;

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

(d) Cancellation of a empanelment process;

(e) Applicability of the provisions of confidentiality.

v. Form of Appeal

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

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

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

vi. Fee for filling appeal

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

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

vii. Procedure for disposal of appeal

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

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

Authority, as the case may be, shall,-

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

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

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

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

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

Any person participating in a empanelment process shall-

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

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

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

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

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

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

g) Disclose conflict of interest, if any; and

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

17. Conflict of interest:-

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

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

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

a. Have controlling partners/shareholders in common; or

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

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

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

e. The Bidder participates in more than one Bid in a bidding process. Participation by a Bidder in more than one Bid will result in the disqualification of all Bids in which the Bidder is involved. However, this does not limit the inclusion of the same subcontractor, not otherwise participating as a Bidder, in more than one Bid; or

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

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

18. <u>JURISDICTION</u>

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

Managing Director
Rajasthan Medical Services Corporation

Annexure - 1

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

Bank Copy

punjab national bank

DIST. NO.

Branch

Institute Name: Rajasthan Medical Services Corporation, Jaipur

Institute ID: RMSCJ - A/c No. 2246002100024414

Date of Deposit: DD MM YY

DETAILS OF THE SUPPLIER

Supplier Name

Tender Ref. No.

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

Mobile No.

Cash Deposit:

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

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹

Commission ₹ 0 0 0 0 0 - 0 0

Total amount ₹ -

Amount (in words): ₹ _____

Name of the Depositor

Signature

Address for communication

For Bank use only

Acknowledgement

Cashier/Officer

Customer Copy

punjab national bank

DIST. NO.

Branch

Institute Name: Rajasthan Medical Services Corporation, Jaipur

Institute ID: RMSCJ - A/c No. 2246002100024414

Date of Deposit: DD MM YY

DETAILS OF THE SUPPLIER

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

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹

Commission ₹ 0 0 0 0 0 - 0 0

Total amount ₹ -

Amount (in words): ₹ _____

Name of the Depositor

Signature

Address for communication

For Bank use only

Acknowledgement

Cashier/Officer

ANNEXURE- II
Ref. Clause No. 2 (3), 3(h)

ANNUAL TURN OVER STATEMENT

The Annual Turnover of M/s._____ for the past three years are given below and certified that the statement is true and correct.

S.No.	Years	Turnover in Lacs (Rs)
1	2017-18	
2	2018-19	
3	2019-20	
Total		**Rs.** **Lacs**
Average turnover per annual		**Rs.** **Lacs**

Or

S.No.	Years	Turnover in Lacs (Rs)
1	2018-19	
2	2019-20	
3	2020-21	
Total		**Rs.** **Lacs**
Average turnover per annual		**Rs.** **Lacs**

Date:

Seal:

Siganture of Auditor/
Chartered Accountant
(Name in Capital)

ANNEXURE III
Ref. Clause No: 3 (e)

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

Name of the Laboratory : _____

Address:_____

_____

_____

Types of Samples Analysed No. of Samples Analysed during

(2018-19, 2019-20 and 2020-21)

01. Tablets / Capsules / Pessaries/Dry Powders

02. Injectables

03. Liquid Preparations

04. Ointments / Creams / Gels

05. Others (Specify)

06. Surgicals (Specify item names)

07. Sutures (Specify types)

08. Implants

09. Devices

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

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

PERSONNEL IN QC DEPARTM ENT

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

Signature :

Date :

Nam e of the Lab :

Office Seal :

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

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

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

Signature :

Name of the Lab :

Date :

Official Seal:

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

FACILITIES IN THE MICROBIOLOGICAL SECTION

I. LIST OF STOCK CULTURES AVAILABLE

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

Signature :

Name of the Lab :

Date :

Official Seal:

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

LISTOF REFERENCES SAMPLES ALONG WITH THEIR DATE OF PROCUREMETN AND QUANTITIES

Signature :

Name of the Lab :

Date :

Official Seal:

Affidavit

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

ANNEXURE – V
Ref. Clause No: 3(k)

DECLARATION FORM

1. I (Name of the Bidder) S/O_____, Age_____, resident of_____, am proprietor /Partner/Director having our office at_____ and the approved drug testing laboratory at_____do hereby declare that I have carefully read all the conditions of BID of Rajasthan Medical Services Corporation Ltd., Jaipur, for the BIDs floated for empanelment of approved drugs testing laboratories for analysis of drugs. (ending on **30.06.2024**) 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(350)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-07/2022/866 Dated :30.03.2022

6. For the empanelment of analytical testing laboratories for the test and analysis of DRUGS (Ending on **30.06.2024**) for Rajasthan medical services corporation and accept all conditions of bid, including amendments if any.

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

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

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

10. Bank detail for e banking :-

    Name of account holder ……

(Affidavit Page2)

    Full name of Bank with Branch ……

    A/c no. with full digits……..

    IFSC code ……..

(Deponent)

Signature :

Date :

Name of the Lab :

Office Seal :

Verification

I……..S/o……(Designation)…….

Affirm on oath that the contents/information from para 1 to 10 as mentioned above, are true & correct to the best of my knowledge and nothing is hidden. I also declare on oath, that if any information furnished by me as above is found wrong, false, forged or fabricated; the Corporation will be at liberty to cancel the Bid and forfeiting the Bid Security deposit and or performance security, for which I shall be solely responsible and the laboratory / firm may be Debarred/Banned/ prosecuted for the same

(Name of Deponent & Signature)

ATTESTED BY NOTARY PUBLIC

ANNEXURE – VI
Ref.Clause No: 3

(l)

DETAILS OF LABORATORY

1. Name of the Laboratory & Full Address :

   Phone No (landline) :

   Fax :

   E-mail :

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

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

   If yes give details of address, license number etc.

4. Date of Inception :

5. Approval No. & Date :

6. Issued by :

7. Valid up to :

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

   or

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

10. Name of the authorized signatory :

11. Specimen Signature of the authorized Signatory :

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

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

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

S. No.	Code No.	Name of Drug		Tests to be performed	Test parameters proposed to be carried out by bidder
1.	694	Inj. Butorphanol tartrate USP 1mg/ml 1ml Size	1	Description	
			2	Identification (by TLC)	
			3	pH	
			4	Becterial endotoxins	
			5	Particulate matter (by Particle counter)	
			6	Volume in container	
			7	**Assay**: (by HPLC)	
			8	Sterility	
2.	695	Inj. Diclofenac Sodium aqueous 75mg/ml 1ml Size, IV & IM use	1	Description	
			2	Identification (by TLC)	
			3	pH	
			4	Particulate matter	
			5	Extractable volume	
			6	**Assay**: (by HPLC)	
			7	Sterility	
3.	696	Paracetamol Infusion IP 1%w/v 100ml Size	1	Description	
			2	Identification (by HPLC)	
			3	pH	
			4	Light absorption (by UV)	
			5	Related substances (by HPLC)	
			6	Becterial endotoxins	
			7	Particulate matter (by Particle counter)	
			8	Extractable volume	
			9	**Assay:** (by HPLC)	
			10	Sterility	
4.	697	Ketorolac Tromethamine Dispersible Tablet IP 10 mg (each Uncoated Dispersable tablet Contains Ketorolac Tromethamine IP 10 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Dissolution (by UV)	
			5	Uniformity of content (by UV)	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by HPLC)	
5.	698	Tab. Baclofen 10 mg, IP (Each Uncoated Tablet contains Baclofen IP 10 mg)	1	Description	
			2	Identification A (by TLC)	
			3	Identification B (by HPLC)	
			4	Average weight	

			5	Lactam (by HPLC)	
			6	Dissolution (by HPLC)	
			7	Uniformity of content (by HPLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
6.	699	Tab. Tizanidine Hydrochloride 2mg IP (Each Uncoated Tablets contains Tizanidine Hydrochloride IP 2 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Dissolution (by UV)	
			5	Uniformity of content (by HPLC)	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by HPLC)	
7.	700	Tab. Dexamethasone IP 4 mg (Each Uncoated Tablet contains Dexamethasone IP 4 mg)	1	Description	
			2	Identification A (by IR)	
			3	Identification B (by HPLC)	
			4	Identification C (Chemical)	
			5	Average weight	
			6	Related substances (by HPLC)	
			7	Uniformity of content (by HPLC)	
			8	Disintegration test	
			9	Contents of Packaged Dosage Forms	
			10	**Assay:** (by HPLC)	
8.	701	Tab Lamotrigine IP 50 mg (Each Sustained Release Tablets contains Lamotrigine IP 50 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Related substances (by HPLC)	
			5	Uniformity of weight	
			6	Uniformity of content (by HPLC) if tablets other than film coated	
			7	Dissolution: (BYHPLC)	
				1st stage	
				2nd stage	
				3rd stage	
				4th stage	
			8	Contents of Packaged Dosage Forms	
			9	**Assay: (by HPLC)**	
9.	702	Tab Divalproex Extended Release IP 250 mg (Each Extended Release Film Coated Tablet contains Divalproex Sodium IP Equivalent to Valproic acid 250 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	**Dissolution:**	
				1st stage	
				2nd stage	
				3rd stage	
				4th stage	
			6	Contents of Packaged Dosage Forms	

			7	**Assay:** (by HPLC)	
10.	703	Tab. Oxcarbazepine IP 150 mg (Each Film Coated Tablet contains Oxcarbazepine IP 150 mg)	1	Description	
			2	Identification A (by HPLC)	
			3	Identification B (by UV)	
			4	Average weight	
			5	Related substances (by HPLC)	
			6	Uniformity of weight	
			7	Dissolution (by UV)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
11.	704	Tab. Lacosamide 100 mg (Each Film Coated Tablet contains Lacosamide 100 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Disintegration test	
			6	Contents of Packaged Dosage Forms	
			7	Assay: (by HPLC)	
12.	705	Tab Topiramate IP 25 mg (Each Film Coated Tablet contains Topiramate IP 25 mg)	1	Description	
			2	Identification A (by IR)	
			3	Identification B (by HPLC)	
			4	Average weight	
			5	Related substances (by HPLC)	
			6	Uniformity of weight	
			7	Dissolution (by HPLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
13.	706	Tab. Amoxycillin 250 mg + Calvulanic Acid 125 mg IP (Each Film Coated Tab. Contain Amoxycillin Trihydrate IP 250 mg & Potassium Clavulanate IP 125 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Water	
			6	**Uniformity of content: Clavulanic acid (by HPLC)**	
			7	**Dissolution:**	
				Amoxycillin (by HPLC)	
				Clavulanic acid (by HPLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:**	
				Amoxycillin (by HPLC)	
				Clavulanic acid (by HPLC	
14.	707	Inj. Piperacillin 2 gm + Tazobactom 250mg USP	1	Description	
			2	Identification (by HPLC)	
			3	Identification (by HPLC)	
			4	pH	
			5	Related substances (by HPLC)	
			6	Water	

			7	Bacterial endotoxins	
			8	Average net content	
			9	Uniformity of weight	
			10	Clarity of solution test a and b	
			11	Particulate matter	
			12	**Assay:**	
				Piperacillin (by HPLC)	
				Tazobactum (by HPLC)	
			12	Sterility	
15.	708	Inj. Ceftriaxone 1 gm + Tazobactum 125 mg	1	Description	
			2	**Identification of:**	
				Ceftriaxone (by HPLC)	
				Tazobactum (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	**pH**	
			6	**Related substances (by HPLC)**	
			7	**Water**	
			8	Clarity of solution test a and b	
			9	Particulate matter	
			10	Bacterial endotoxins	
			11	**Assay:**	
				Ceftriaxone (by HPLC)	
				Tazobactum (by HPLC)	
			12	Sterility	
16.	709	Cefadroxil Dispersible tablet IP 250mg (each uncoated Dispersible tablet contain Cefadroxil IP equivalent to anhydrous cefadroxil 250 mg)	1	Description	
			2	Identification (by TLC)	
			3	Average weight	
			4	Related substances (by HPLC)	
			5	Uniformity of weight	
			6	Dissolution (by UV)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
17.	710	Tab. Cefadroxil 500 mg	1	Description	
			2	Identification (by TLC)	
			3	Average weight	
			4	Related substances (by HPLC)	
			5	Uniformity of weight	
			6	Dissolution (by UV)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
18.	711	Ofloxacin Oral Suspension IP (Each 5ml contains Ofloxacin IP 100 mg) 30 ml Size	1	Description	
			2	Identification (by HPLC)	
			3	Contents of Packaged Dosage Forms	
			4	Weight per ml	

			5	**Assay:** (by HPLC)	
			6	Identification of colour	
			7	**Microbial Examination**	
				Total aerobic count	
				Total fungal count	
				E. coli	
19.	712	Tab. Levofloxacin IP 500 mg (Each Film Coated Tablet containsLevofloxacin Hemihydrate IP 500 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Related substances (by HPLC)	
			6	Dissolution (by UV)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
			9	Identification of colour	
20.	713	Tab. Faropenem Sodium 200 mg (Each Film coated Tablet contains Faropenem Sodium equivalent to Faropenem Sodium 200 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Dissolution (by UV)	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by HPLC)	
21.	714	Inj. Clindamycin phosphate IP 300 mg	1	Description	
			2	Identification A (by TLC)	
			3	Identification B (by HPLC)	
			4	pH	
			5	Related substances (by HPLC)	
			6	Becterial endotoxins	
			7	Particulate matter	
			8	Extractable volume	
			9	Assay: (by HPLC)	
			10	Sterility	
22.	715	Inj. Imipenem + Cilastatin 500mg/500mg IP Powder for Solution	1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	pH	
			6	Clarity of solution test a and b	
			7	Particulate matter	
			8	Bacterial endotoxins	
			9	Loss on drying	
			10	**Assay:** (by HPLC)	
			11	Sterility	
23.	716	Inj. Polymixin Sulphate B USP 5 Lac I.U.	1	Description	
			2	Constituted solution(clarity of Solution)	

			6	Identification (by TLC)	
			7	Pyrogen	
			5	Average net content	
			6	Uniformity of weight	
			7	Particulate matter in Injection	
			8	Residue on ignition	
			9	**Assay:** (by microbial)	
			10	Sterility	
24.	717	Inj. Meropenem IP 250 mg	1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	pH	
			6	Related Substances (by HPLC)	
			7	Content of Sodium (by FP/AAS)	
			8	Bacterial endotoxins	
			9	Loss on drying	
			10	Clarity of solution test a and b	
			11	Particulate matter	
			12	**Assay:** (by HPLC)	
			13	Sterility	
25.	718	Inj. Colistimethate IP 1M IU Powder for Solution	1	Description	
			2	Identification A (by TLC)	
			3	Identification B (Chemical)	
			4	Identification C (Chemical)	
			5	Identification D (Chemical)	
			6	Average net content	
			7	Uniformity of weight	
			8	pH	
			9	free colistin	
			10	Bacterial endotoxins	
			11	Loss on drying	
			12	Clarity of solution test a and b	
			13	Particulate matter	
			14	**Assay:** (by Microbiological assay)	
			15	Sterility	
26.	719	Inj. Liposomol Amphotericine B 50 mg	1	Description	
			2	pH	
			3	Loss on drying	
			4	Bacterial endotoxins	
			5	Average weight	
			6	Uniformity of weight	
			7	Particulate matter	
			8	Clarity of solution A and B	
			9	**Assay:** (by Microbiological assay)	

			10	Sterility	
27.	720	Inj. Voriconazole 200mg/Vial	1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	pH	
			6	Related substances (by HPLC)	
			7	Bacterial endotoxins	
			8	Clarity of solution test a and b	
			9	Particulate matter	
			10	**Assay:** (by HPLC)	
			11	Sterility	
28.	721	Tab. Terbinafine Hydrochloride IP 250 mg	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Related substances (by HPLC)	
			6	Limit of Terbinafine Dimer (by HPLC)	
			7	Dissolution (by UV)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
29.	722	Tab. Valganciclovir 450 mg	1	Description	
			2	Identification (by HPLC)	
			3	Identification (by UV)	
			4	Average weight	
			5	Uniformity of weight	
			6	Organic Impurities (By HPLC)	
			7	Dissolution (by HPLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
30.	723	Tab. Entecavir IP 0.5 mg (Each Film Coated Tablet contains Entecavir IP 0.5 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of content (by HPLC)	
			5	Related substances (by HPLC)	
			6	Dissolution (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
31.	724	Inj. Ganciclovir Sodium 500mg IP (lyophilized powder for reconstitution)		**Ganciclovir Injection IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	pH	
			6	Water	

			7	Bacterial endotoxins	
			8	Clarity of solution test a and b	
			9	Particulate matter	
			10	**Assay:** (by HPLC)	
			11	Sterility	
32.	725	Capsule Procarbazine Hydrochloride USP 50 mg (Each Capsule contains Procarbazine Hydrochloride USP 50 mg)		**Procarbazine hydrochloride capsules IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	Dissolution (by UV)	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by Polarographic Potential)	
33.	726	Inj. Bendamustine 100 mg		**Bendamustine Injection IP**	
			1	Description	
			2	Identification A (by HPLC)	
			3	Identification B (Chemical)	
			4	Average net content	
			5	Uniformity of weight	
			6	pH	
			7	Water	
			8	Related substances (by HPLC)	
			9	Bacterial endotoxins	
			10	Clarity of solution test a and b	
			11	Particulate matter	
			12	**Assay:** (by HPLC)	
			13	Sterility	
34.	727	Tab. Capecitabine IP 500 mg (Each Film Coated Tablet contains Capecitabine IP 500 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Dissolution (by HPLC)	
			6	Related substances (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
35.	728	Tab Letrozole IP 2.5 mg (Each Film Coated Tablet contains Letrozole **IP** 2.5 mg)		**Letrozole Tablets IP**	
			1	Description	
			2	Identification A (by TLC)	
			3	Identification B (by HPLC)	
			4	Average weight	
			5	Uniformity of content (by HPLC)	
			6	Dissolution (by HPLC)	
			7	Related substances (by HPLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	

36.	729	Capsule Temozolomide IP 100 mg (Each hard Gelatin Capsule contains Temozolomide IP 100mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	Disintegration test	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by HPLC)	
37.	730	Inj. Bortezomib 2mg		**Bortezomib Injection IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	Appearance of solution	
			6	pH	
			7	Related substances (by HPLC)	
			8	**Tertiary Butanol (by GC) if present**	
			9	Bacterial endotoxins	
			10	Clarity of solution test a and b	
			11	Particulate matter	
			12	**Assay:** (by HPLC)	
			13	Sterility	
38.	731	Tab Abiraterone Acetate IP 250 mg (Each Uncoated Tablet contains Abiraterone Acetate IP 250 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Dissolution (by HPLC)	
			6	Related substances (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
39.	732	Capsule Lomustine IP 40 mg (Each Capsule contains Lomustine IP 40 mg)	1	Description	
			2	Identification A (by IR)	
			3	Identification B (by Melting point)	
			4	Average net content	
			5	Uniformity of weight	
			6	Related substances (by TLC)	
			7	Related substances (by HPLC)	
			8	Disintegration test	
			9	Contents of Packaged Dosage Forms	
			10	**Assay:** (by UV)	
40.	733	Cap Thalidomide USP 100 mg (Each Hard Gelatin Capsule contains Thalidomide USP 100 mg)		Description	
			1	Identification A (by TLC)	
			2	Identification B (by HPLC)	
			3	Average net content	
			4	Uniformity of dosage unit (Weight Variation)	
			5	Dissolution (By HPLC)	

			6	Organic Impurities (By HPLC)	
			7	**Assay:** (By HPLC)	
			8	**Microbial enumeration tests and tests for specified Microorganisms**	
				Total aerobic count	
				Total Combined molds and yeasts counts	
				E. coli	
41.	734	Inj. Bevacizumab 400 mg		NIB	
42.	735	Inj. Bevacizumab 100 mg		NIB	
43.	736	Tab. Cyclophosphamide IP 50 mg (Each Sugar Coated Tablet contains Cyclophosphamide IP 53.5 mg equivalent to Anhydrous Cyclophosphamide 50 mg)	1	Description	
			2	Identification A (by IR)	
			3	Identification B (Chemical)	
			4	Identification C (Chemical)	
			5	Average weight	
			6	Uniformity of Weight	
			7	Acidity	
			8	Disintegration test	
			9	Related substances (by TLC)	
			10	Contents of Packaged Dosage Forms	
			11	**Assay:** (by Titration)	
44.	737	Tab. Gefitinib IP 250 mg (Each Film Coated Tablet contains Gefitinib IP 250 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Dissolution (by UV)	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by HPLC)	
45.	738	Capsule Mycophenolate mofetil IP 250 mg (Each Capsule Conatin Mycophenolate mofetil **IP** 250 mg)		**Mycophenolate mofetil Capsules IP**	
			1	Description	
			2	Identification A (by HPLC)	
			3	Identification B (by UV)	
			4	Average net content	
			5	Limit of degradation product (by HPLC)	
			6	Uniformity of weight	
			7	Related substances (by HPLC)	
			8	Limit of Z-Mycophenolate mofetil (HPLC)	
			9	Dissolution (by HPLC)	
			10	Water	
			11	Contents of Packaged Dosage Forms	
			12	**Assay:** (by HPLC)	
46.	739	Capsule Tacrolimus IP 0.5 mg (Each Hard Gealtin Capsule Tacrolimus IP 0.5 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	**Related substances (by HPLC):**	
			6	Dissolution (by HPLC)	

			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
47.	740	Tab. Mycophenolate Sodium 360 mg (Each Enteric Coated tablet Contain Mycophenolate Sodium 360 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Identification (by UV)	
			4	Average weight	
			5	Uniformity of content (by HPLC)	
			6	Disintegration test /Dissolution (By UV)	
			7	Organic Impurities (By HPLC)	
			8	Z-Mycophenolate mofetil	
			9	Contents of Packaged Dosage Forms	
			10	**Assay:** (by HPLC)	
48.	741	Tab. Bicalutamide IP 50 mg (Each Film Tablet contains Bicalutamide **IP** 50 mg)		**Bicalutamide Tablets IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Related substances (by HPLC)	
			6	Dissolution (by UV)	
			7	Water	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
49.	742	Tab. 6 Thioguanine USP 40 mg (Each Uncoated Tablet contains 6 Thioguanine USP 40 mg)		**6 Thioguanine Tablets IP**	
			1	Description	
			2	Identification A (by IR)	
			3	Identification B (by HPLC)	
			4	Average weight	
			5	Uniformity of weight	
			6	Related substances (by HPLC)	
			7	Dissolution (by UV)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
50.	743	Inj Zoledronic acid IP 4mg		**Zoledronic acid Injection IP (Powder form instead of liquid)**	
			1	Description	
			2	Identification (by HPLC)	
			3	Average net content	
			4	Uniformity of weight	
			5	pH	
			6	Bacterial endotoxins	
			7	Clarity of solution test a and b	
			8	Particulate matter	
			9	**Assay:** (by HPLC)	
			10	Sterility	
51.	744	Inj. n Butyl Alcohol 0.26mg/5ml, Citric Acid 2.5mg/5ml, and Sod.	1	Description	
				Identification of:	

		Chloride Solution 5 ml Size	2	n-Butyl Alcohol (by GLC)	
			3	Citric Acid	
			4	Sodium and Chloride	
			5	pH	
			6	Particulate matter	
			7	Extractable volume	
			8	**Assay**:	
				n-Butyl Alcohol (by GLC)	
				Citric Acid (by Ion Chromatography)	
				Sodium Chloride (by Titration)	
			9	Sterility	
52.	745	Tab Ethamsylate BP 500 mg (Each Uncoated Coated Tablets contains Ethamsylate BP 500 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Disintegration test	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by HPLC)	
53.	746	Feracrylum 1%w/w Sterile Solution 100 ml	1	Description	
			2	Identification of Feracrylum (Chemical)	
			3	pH	
			4	Relative Viscosity at 25C	
			5	Unreacted protein	
			6	Activity of Feracrylum	
			7	Content of Iron	
			8	Extractable volume	
			9	Assay (Titration)	
			10	Sterility	
54.	747	Inj Tranexamic Acid IP 100mg/ml 5ml Size	1	Description	
			2	Identification A (by IR)	
			3	Identification B (Chemical)	
			4	pH	
			5	Related substances (by HPLC)	
			6	Bacterial endotoxins	
			7	Particulate matter	
			8	Extractable volume	
			9	**Assay**: (by Titration)	
			10	Sterility	
55.	751	Tab. Clonidine Hydrochloride USP 0.1 mg (Each Tablet contains Clonidine Hydrochloride USP 0.1 mg)		**Clonidine Hydrochloride Tablets IP**	
			1	Description	
			2	Identification A (by UV)	
			3	Identification B (Chemical)	
			4	Average weight	
			5	Uniformity of content (by UV)	
			6	Disintegration test	

			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
56.	752	Tab. Sotalol Hydrochloride USP/BP 40mg (Each Film Coated Tablet contains Sotalol Hydrochloride USP/BP 40mg)	1	Description	
			2	Identification (by UV)	
			3	Identification (by TLC)	
			4	Average weight	
			5	Uniformity of weight	
			6	Related substances (by HPLC)	
			7	Disintegration test	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
57.	753	Inj. Esmolol hydrochloride 10mg/ml 10ml Size		**Esmolol hydrochloride Injection IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	pH	
			4	Bacterial endotoxins	
			5	Particulate matter	
			6	Extractable volume	
			7	**Assay**: (by HPLC)	
			8	Sterility	
58.	754	Inj. Sodium Nitroprusside 25mg/ml 2ml Size		**Sodium Nitroprusside Injection IP**	
			1	Description	
			2	Identification A (by UV)	
			3	Identification B (Chemical)	
			4	Identification C (Chemical)	
			5	Bacterial endotoxins	
			6	Particulate matter	
			7	Extractable volume	
			8	**Assay**: (by HPLC)	
			9	Sterility	
59.	755	Tab. Carvedilol 3.125 mg		**Carvedilol Tablets IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Dissolution (by HPLC)	
			5	Uniformity of content (by HPLC)	
			6	Related substances (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
60.	756	Tab. Rosuvastatin IP 20 mg (Each Film Coated Tablet contains Rosuvastatin Calcium IP equivalent to Rosuvastatin 20 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Dissolution (by HPLC)	
			5	Uniformity of weight	
			6	Related substances (by HPLC)	

			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
61.	757	Tab. Rosuvastatin 10 mg	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Dissolution (by HPLC)	
			5	Uniformity of content (by HPLC)	
			6	Related substances (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
62.	758	Tab. Sacubitril 24 mg and Valsartan 26 mg	1	Description	
				Identification of:	
			2	Sacubitril (by HPLC)	
			3	Valsartan (by HPLC)	
			4	Average weight	
			5	**Uniformity of content (by HPLC)**	
				Sacubitril (by HPLC)	
				Valsartan (by HPLC)	
			6	Disintegration test	
			7	**Assay: (by HPLC)**	
				Sacubitril (by HPLC)	
				Valsartan (by HPLC)	
			8	Identification of colour	
63.	759	Powder Clotrimazole 1%w/w 30 gm	1	Description	
			2	Identification (by HPLC)	
			3	Content of 2-Chlotritanol (by HPLC)	
			4	Contents of Packaged Dosage Forms	
			5	**Assay:** (by HPLC)	
64.	760	Cream Terbinafine 1%w/w IP (10 gm Tube)		**Terbinafine Cream IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	pH	
			4	Related substances (by HPLC)	
			5	Contents of Packaged Dosage Forms	
			6	**Assay:** (by HPLC)	
65.	761	Olopatadine Hydrochloride Ophthalmic Solution 0.1% w/v IP (E/D) 5ml Size		**Olopatadine Hydrochloride Ophthalmic Solution IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	pH	
			4	Related substances A (by HPLC)	
			5	Related substances B (by HPLC)	
			6	Contents of Packaged Dosage Forms	
			7	Sterility	
			8	**Assay:** (by HPLC)	
66.	762	Ointment Mupirocin IP		**Mupirocin Ointment IP**	

		2%	1	Description	
			2	Identification A (by TLC)	
			3	Identification A (by HPLC)	
			4	Minimum fill	
			5	pH	
			6	Related substances (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
			9	Microbial enumeration test	
67.	763	Tab Doxylamine Succinate 20 mg & Pyridoxine Hydrochloride 20 mg (Each Enteric Coated Tablet contains Doxylamine Succinate USP 20 mg & Pyridoxine Hydrochloride IP 20 mg)		Description	
			1	**Identification of:**	
				Doxylamine Succinate (by HPLC)	
				Pyridoxine hydrochloride (by HPLC)	
			2	Average weight	
			3	**Uniformity of content (by HPLC)**	
				Doxylamine Succinate	
				Pyridoxine hydrochloride	
			4	Disintegration test	
			5	**Assay: (by HPLC)**	
				Doxylamine Succinate	
				Pyridoxine hydrochloride	
			6	Identification of colour	
68.	764	Inj. Prochlorperazine mesylate 12.5mg/ml 5ml Size		Description	
			1	Identification A (by IR)	
			2	Identification B (Chemical)	
			3	pH	
			4	Related substances (by TLC)	
			5	Particulate matter	
			6	Extractable volume	
			7	**Assay:** (by UV)	
			8	Sterility	
69.	765	Probiotic Sachets 1 gm Size (Each Gram Sachet contains Saccharomyces Boulardii 250mg & Lactic acid Bacillus 150 million spores)	1	Description	
				Identification of:	
			2	Saccharomyces Boulardii	
			3	Lactic acid Bacillus	
			4	Average net content	
			5	Uniformity of weight	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by Microbiological assay)	
				Saccharomyces Boulardii	
				Lactic acid Bacillus	
70.	766	Tab. Mesalamine USP 1.2 gm Enteric Coated (Each Enteric Coated Prolonged Release Tablet Contain Mesalamine USP 1.2 gm)		**Mesalamine Prolonged Release Tablets IP**	
			1	Description	
			2	Identification (by IR)	
			3	Average weight	

			4	Related substances (by HPLC)	
			5	Impurities A and C (by HPLC)	
			6	Impurities K (by HPLC)	
			7	Uniformity of weight	
			8	**Dissolution:**	
				1st stage	
				2nd stage	
				3rd stage	
				4th stage	
			9	Contents of Packaged Dosage Forms	
			10	**Assay:** (by HPLC)	
71.	768	Inj. Cis Atracurium Besylate 2 mg/ml in 5 ml vial		**Atracurium Besylate Injection IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	pH	
			4	Related substances (by HPLC)	
			5	Extractable volume	
			6	Particulate matter	
			7	Bacterial endotoxins	
			8	**Assay:** (by HPLC)	
			9	Sterility	
72.	769	Acyclovir Eye Ointment IP 3%w/w 5gm Size	1	Description	
			2	Identification A (by UV)	
			3	Identification B (by TLC)	
			4	Guanine (by TLC)	
			5	Uniformity of weight	
			6	**Assay:** (by UV)	
			7	Sterility	
73.	770	Eye drop Moxifloxacin 0.5%w/v Ophthalmic Solution IP 5ml Size	1	Description	
			2	Identification (by HPLC)	
			3	pH	
			4	Related substances (by HPLC)	
			5	Contents of Packaged Dosage Forms	
			6	**Assay:** (by HPLC)	
			7	Sterility	
74.	771	Chloramphenicol 1%w/w Eye ointment IP, 3gm Size	1	Description	
			2	Identification A (by IR)	
			3	Identification B (Chemical)	
			4	Minimun fill	
			5	Uniformity of weight	
			6	**Assay:** (by HPLC)	
			7	Sterility	
75.	772	Natural Micronised Progesteron Soft gelatin Capsule 200 mg (Each Soft Gelatin Capsule	1	Description	
			2	Identification (by HPLC)	
			3	Disintegration Test	

		contains Progesteron IP 200 mg)	4	Average Net Content	
			5	Uniformity of Weight	
			6	Assay (By HPLC)	
			7	Microbial enumeration test	
76.	773	Tab Cabergoline IP 0.5mg (Each Uncoated Coated Tablet contains abergoline IP 0.5mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Dissolution (by HPLC)	
			5	Uniformity of content (by HPLC)	
			6	Related substances (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
77.	775	Leurprolide Acetate depot 3.75 mg	1	Description	
			2	Identification (by HPLC)	
			3	Water	
			4	Solubility	
			5	pH	
			6	Extractable volume	
			7	Particulate matter	
			8	Bacterial endotoxins	
			9	Related Substances (by HPLC)	
			10	Average Fill Weight	
			11	Uniformity of dosage unit	
			12	Assay (by HPLC)	
			13	Sterility	
78.	776	Leurprolide Acetate depot 11.25 mg	1	Description	
			2	Identification (by HPLC)	
			3	Water	
			4	Solubility	
			5	pH	
			6	Extractable volume	
			7	Particulate matter	
			8	Bacterial endotoxins	
			9	Related Substances (by HPLC)	
			10	Assay (by HPLC)	
			11	Sterility	
79.	777	Tab. Levosulpiride 25 mg (Each uncoated Tablet contains Levosulpiride 25 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Uniformity of content (by HPLC)	
			6	Disintegration test	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
80.	778	Tab. Lorazepam IP 2 mg	1	Description	

		(Each Uncoated Tablet contains Lorazepam IP 2 mg)	2	Identification A (by UV)	
			3	Identification B (by TLC)	
			4	Average weight	
			5	Dissolution (by UV)	
			6	Uniformity of content (by UV)	
			7	Related substances (by TLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by UV)	
81.	779	Tab. Zolpidem 5 mg	1	Description	
			2	Identification A (by IR)	
			3	Identification B (by HPLC)	
			4	Average weight	
			5	Dissolution (by HPLC)	
			6	Uniformity of content (by HPLC)	
			7	Related substances (by HPLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
82.	780	Tab. Acebrophylline 100 mg	1	Description	
			2	**Identification**	
				Acephylline	
			3	Average weight	
			4	Disintegration test	
			5	Uniformity of weight	
			6	Contents of Packaged Dosage Forms	
			7	**Assay:** (by HPLC)	
				Acephylline	
83.	781	Ringer Acetate Infusion 500 ml	1	Description	
			2	Identification A (Sodium)	
			3	Identification B (Chloride)	
			4	Identification C (Calcium)	
			5	Identification D (Potassium)	
			6	Identification E (Acetate)	
			7	pH	
			8	Extractable volume	
			9	Particulate Contamination (by Particle Counter)	
			10	Bacterial endotoxins	
			11	Heavy Metals	
			12	**Assay**	
				Total Chloride	
				Sodium	
				Potassium	
				Calcium	
				Acetate	
			13	Sterility	
84.	782	Sodium Chloride	1	Description	

		0.45%w/v Polypack 500 ml	2	Identification A (Chemical)	
			3	Identification B (Chemical)	
			4	Heavy metals	
			5	pH	
			6	Particulate contamination (by particle counter)	
			7	Extractable volume	
			8	Bacterial endotoxins	
			9	**Assay:** (Titration)	
			10	Sterility	
85.	783	Tab. Savelamer Carbonate 400 mg (Each Film Coated Tablet contains Savelamer Carbonate 400 mg)	1	Description	
			2	Identification A (by HPLC)	
			3	Average Weight	
			4	Uniformity of Weight	
			5	Disintegration time	
			6	Contents of Packaged Dosage Forms	
			7	Assay (by HPLC)	
			8	Identification of Colour	
86.	784	Tab Sodium Bicarbonate USP 1 gm (Each Film Coated Tablets contains Sodium Bicarbonate USP 1 gm)	1	Description	
			2	Identification (by Chemical)	
			3	Disintegration	
			4	Average weight	
			5	Uniformity of dosage unit (weight variation)	
			6	**Assay:** (by Titration)	
87.	785	Tab. Levamisol Hydrochloride IP 50 mg (Each Uncoated tablet contain levamisol Hydrochloride IP 50 mg)	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Dissolution (by UV)	
			5	Uniformity of weight	
			6	Related substances (by TLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by Titration)	
88.	786	Tab. Phenazopyridine 5 mg		**Phenazopyridine Tablets USP**	
			1	Description	
			2	Identification A (by UV)	
			3	Identification B (by HPLC)	
			4	Average weight	
			6	**Organic Impurities (By HPLC)**	
			7	Content uniformity (by HPLC)	
			8	Dissolution (by UV)	
			9	**Assay:** (By HPLC)	
89.	787	Tab. Dutasteride 0.5 mg		**Dutasteride Capsules IP**	
			1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Dissolution (by HPLC)	

			5	Related substances (by HPLC)	
			6	Uniformity of content (by HPLC)	
			7	**Assay:** (By HPLC)	
90.	788	Syp. Alkylizer 1.4 gm/5 ml (100 ml) (Disodium Hydrogen Citrate)	1	Description	
			2	Identification of sodium and citrate	
			3	Weight per ml	
			4	pH	
			5	Contents of Packaged Dosage Forms	
			7	**Assay:** (by Titration)	
			8	Identification of colour	
			9	**Microbial Examination**	
				Total aerobic count	
				Total fungal count	
				E. coli	
91.	789	Inj. Ferric Carboxymaltose 50 mg/ml 10 ml size	1	Description	
			2	Identification B (by Chemical)	
			3	Identification C (by Chemical)	
			4	pH	
			5	Weight per ml	
			6	Average Molecular Weight (GPC)	
			7	Limit For Iron (by Titrimetry)	
			8	Poly maltose Content (UV)	
			9	Chloride Content	
			10	Osmolarity	
			11	Bacterial endotoxins	
			12	Particulate matter (by particle counter)	
			13	Extractable volume	
			14	Assay (HPLC)	
			15	Sterility	
92.	790	Multi vitamin Syrup	1	Description	
			2	pH	
			3	Contents of Packaged Dosage Forms	
				Assay:	
			4	Vitamin A (by UV)	
			5	Vitamin D3 (by HPLC)	
			6	Thiamine hydrochloride (by UV)	
			7	Riboflavin sodium phosphate (by UV)	
			8	Pyridoxine hydrochloride (by UV)	
			9	Cyanocobalamin (by Microbiological assay)	
			10	D-Panthenol (by UV)	
			11	Niacinamide (by UV)	
			12	L-Lysine hydrochloride (by UV)	
			13	Identification of colour	
			14	Weight per ml	
			15	**Microbial Examination**	
				Total aerobic count	

				Total fungal count	
				E. coli	
93.	791	Intravenous Fat Emulsion 20% w/v 250ml size	1	Description	
			2	Nominal Volume	
			3	Extractable volume	
			4	pH	
			5	Globule Size (by Microscope)	
			6	Peroxide Value	
			7	Free Acid Value	
			8	Bacterial endotoxins	
			9	Assay	
				Content of Long chain Triglycerides	
				Content of Medium chain Triglycerides	
				Glycerol	
			10	Sterility	
94.	792	Tab. Pyridostigmine USP 60 mg (Each Tablet contains Pyridostigmine USP 60 mg)		**Pyridostigmine Tablets IP**	
			1	Description	
			2	Identification A (by UV)	
			3	Identification B (by TLC)	
			4	Identification C (by Chemical)	
			5	Average weight	
			6	Uniformity of weight	
			7	Related substances (by HPLC)	
			8	Disintegration time	
			9	Contents of Packaged Dosage Forms	
			10	**Assay:** (by UV)	
95.	793	Inj. Caffeine Citrate USP 20mg/ml (equivalent to 10 mg caffeine base/ml) 3ml Size	1	Description	
			2	Identification A (by HPLC)	
			3	Identification B (by Chemical)	
			4	Identification C (by Chemical)	
			5	Colour and Clarity of solution	
			6	pH	
			7	Organic Impurities (By HPLC)	
			8	Bacterial endotoxins	
			9	Particulate matter (by Particle counter)	
			10	Volume in container	
			11	**Assay**: (by HPLC)	
			12	Sterility	
96.	794	Inj. Amino Acid 10% 100ml Size	1	Description	
				Identification (by HPLC)	
			2	pH	
			3	Particulate matter (by particle counter)	
			4	Bacterial endotoxins	
			5	Extinct E	
			6	Microbial Examination	
			7	Assay of Amino Acid	

			8	Sterility	
97.	795	Cap. Vitamin E 400 mg		**Vitamin E Capsules USP**	
			1	Description	
			2	Identification A	
			3	Identification B (Optical rotation)	
			4	Identification C (by GLC)	
			5	Average net content	
			6	Uniformity of dosage units (weight variation)	
			7	Disintegration test	
			8	**Assay:** (by GLC)	
98.	796	inj.Poractant Alpha80mg/ml in Pack of 1.5ml			
99.	800	Inj. Liposomol Amphotericine B 50 mg	1	Description	
			2	pH	
			3	Loss on drying	
			4	Bacterial endotoxins	
			5	Average weight	
			6	Uniformity of weight	
			7	Particulate matter	
			8	Clarity of solution A and B	
			9	**Assay:** (by Microbiological assay)	
			10	Sterility	
100.	801	Multistix Test Strip			
101.	NE15	Misoprostol Tablet 600mg	1	Description	
			2	Identification A (by HPLC)	
			3	Average weight	
			4	Uniformity of content (by HPLC)	
			5	Contents of Packaged Dosage Forms	
			6	Disintegration time	
			7	**Assay:** (by HPLC)	
102.	NE17	MTP (Medical Termination of pregnancy Drug Kit(Combipack of 1Tablet Mifeprestone 200mg and 4 tablet of misoprostol 200mcg		**Mifeprestone Tablets**	
			1	Description	
			2	Identification A (by HPLC)	
			3	Identification B (by UV)	
			4	Average weight	
			5	Uniformity of weight	
			6	Dissolution (by UV)	
			7	Related substances (by HPLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
				Misoprostol Tablets	
			10	Description	
			11	Identification A (by HPLC)	
			12	Average weight	
			13	Uniformity of content (by HPLC)	
			14	Contents of Packaged Dosage Forms	

			15	Disintegration time	
			16	**Assay: (**by HPLC)	
103.	NE18	kanamycin Injection 500mg ip(Liquid Form)		**For solution**	
			1	Description	
			2	Identification (by TLC)	
			3	pH	
			4	Kanamycin B (by TLC)	
			5	Particulate matter	
			6	Extractable volume	
			7	Bacterial endotoxins	
			8	**Assay**: (by microbiological)	
			9	Sterility	
104.	NE18	kanamycin Injection 500mg ip(Powder Form)		**For powder for injection**	
			1	Description	
			2	Identification (by TLC)	
			3	pH	
			4	Kanamycin B (by TLC)	
			5	Average net content	
			6	Uniformity of weight	
			7	Clarity of solution test a and b	
			8	Particulate matter	
			9	Bacterial endotoxins	
			10	**Assay**: (by microbiological)	
			11	Sterility	
105.	NE19	kanamycin Injection 1000mg ip(liquid Form)		**For solution**	
			1	Description	
			2	Identification (by TLC)	
			3	pH	
			4	Kanamycin B (by TLC)	
			5	Particulate matter	
			6	Extractable volume	
			7	Bacterial endotoxins	
			8	**Assay**: (by microbiological)	
			9	Sterility	
106.	NE19	kanamycin Injection 1000mg ip(powder Form)		**For powder for injection**	
			1	Description	
			2	Identification (by TLC)	
			3	pH	
			4	Kanamycin B (by TLC)	
			5	Average net content	
			6	Uniformity of weight	
			7	Clarity of solution test a and b	
			8	Particulate matter	
			9	Bacterial endotoxins	
			10	**Assay**: (by microbiological)	
			11	Sterility	

107.	NE20	Levofloxacin Tablet 500mg IP	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Related substances (by HPLC)	
			6	Dissolution (by UV)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
			9	Identification of colours	
108.	NE21	Cycloserine Capsule 250mg IP	1	Description	
			2	Identification A	
			3	Identification B (by HPLC)	
			4	Average net content	
			5	Uniformity of weight	
			6	Dissolution (by HPLC)	
			7	Condensation products (by UV)	
			8	Loss on drying	
			9	Contents of Packaged Dosage Forms	
			10	**Assay:** (by HPLC)	
109.	NE22	Ethionamide Tablets 125mg IP	1	Description	
			2	Identification A (by IR)	
			3	Identification B (by HPLC)	
			4	Average weight	
			5	Uniformity of weight	
			6	Related substances (by HPLC)	
			7	Dissolution (by UV)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
110.	NE23	Ethionamide Tablets 250mg IP	1	Description	
			2	Identification A (by IR)	
			3	Identification B (by HPLC)	
			4	Average weight	
			5	Uniformity of weight	
			6	Related substances (by HPLC)	
			7	Dissolution (by UV)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by HPLC)	
111.	NE24	Capreomycin Injection 500mg		**For powder for injection**	
			1	Description	
			2	Identification A (by UV)	
			3	Identification B (by UV)	
			4	Appearance of solution	
			5	pH	
			6	Capreomycin I content (by HPLC)	
			7	Average net content	
			8	Uniformity of weight	

			9	Clarity of solution test a and b	
			10	Particulate matter	
			11	Bacterial endotoxins	
			12	Loss on drying	
			13	**Assay**: (by microbiological)	
			14	Sterility	
112.	NE25	Moxifloxacin Tablets 400mg	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Dissolution (by HPLC)	
			6	Related substances (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by UV)	
113.	NE26	Clofazimine Capsules 100mg IP	1	Description	
			2	Identification A (by UV)	
			3	Identification B	
			4	Average net content	
			5	Uniformity of weight	
			6	Related substances (by HPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by UV)	
114.	NE28	Clarithromycin Tablets 500mg IP	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Dissolution (by HPLC)	
			6	Related substances (by HPLC)	
			7	Loss on drying	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:** (by UV)	
115.	NE29	Amoxycillin 875 mg + Calvulanic Acid 125 mg Tablets IP	1	Description	
			2	Identification	
				Amoxycillin (by HPLC)	
				Clavulanic acid (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Water	
			6	**Uniformity of content:** Clavulanic acid (by HPLC)	
			7	**Dissolution of**	
				Amoxycillin (by HPLC)	
				Clavulanic acid (by HPLC)	
			8	Contents of Packaged Dosage Forms	
			9	**Assay:**	
				Amoxycillin (by HPLC)	

				Clavulanic acid (by HPLC)	
116.	NE30	Pryidoxine Tablets 100mg IP	1	Description	
			2	Identification A (by UV)	
			3	Identification B (Chemical)	
			4	Average weight	
			5	Related substances (by TLC)	
			6	Uniformity of weight	
			7	Disintegration Time	
			8	Contents of Packaged Dosage Forms	
			9	Assay: (by UV)	
117.	NE31	Hand Rub	1	Description	
			2	Identification (by GLC)	
			3	Identification (by chemical)	
			4	Filled Volume	
			5	Weight per ml	
			6	Assay:	
				2-propanol (by GLC)	
				1-propanol (by GLC)	
				Ethyl-hexadecyl-dimethyl,	
				ammonium ethyl sulfate	
			7	**Microbial Examination:**	
				Total aerobic count	
				Total yeast/Molds count	
				P aeruginosa	
				S aureus	
118.	NE35	Glucose Powder IP (Dextrose Monohydrate) Energy 300 Kcal Carbohydrate 75 gm Of which sugar (Sucrose) 0.00gm Fat and all type of fatty acids 0.00gm Protein: 0.00gm	1	Description	
			2	Identification A	
			3	Identification B	
			4	Appearance of solution	
			5	Solubility	
			6	Acidity or Alkanity	
			7	Specific Optical Rotation	
			8	Arsenic	
			9	Chlorides	
			10	Sulphate	
			11	Sulphite	
			12	Heavy metals	
			13	Barium	
			14	Foreign Sugar, soluble starch and dextrin	
			15	Sulphated Ash	
			16	Water	
119.	172	Enoxaparin Sodium Injection IP 60 mg	1	Description	
			2	Identification A (Chemical)	
			3	Identification B (by UV)	
			4	Identification C (Chemical)	
			5	PH	

			6	Benzyl Alcohol (If Present)	
			7	Free Sulphate (Ion Chromatography)	
			8	Bacterial endotoxins	
			9	Extractable volume	
			10	Particulate matter	
			11	**Assay:** (Anti Factor Xa activity)	
				(Anti Factor IIa activity)	
				Anti factor Xa to Anti Factor Iia ratio	
			12	Sterility	
120.	188	Clopidogrel Tablets IP 75 mg	1	Description	
			2	Identification (by HPLC)	
			3	Average weight	
			4	Uniformity of weight	
			5	Related substances (by HPLC)	
			6	Dissolution (by UV)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by HPLC)	
			9	Identification of colour	
121.	235	Gadodiamide Injection 0.5 mmol/ml Vial	1	Description	
			2	Identification A (by UV)	
			3	Identification B (by HPLC)	
			4	Organic impurities (by HPLC)	
			5	Osmolality and Osmolarity	
			6	pH	
			7	Particulate contamination	
			8	Bacterial endotoxins	
			9	Extractable volume	
			10	**Assay:** (by HPLC)	
			11	Sterility	
122.	244	Compound Benzoin Tincture IP	1	Description	
			2	Identification A- (By TLC)	
			3	Identification B- (By TLC)	
			4	Identification C- (By TLC)	
			5	Identification D- (By TLC)	
			6	Weight per ml	
			7	Ethanol Content	
			8	Total Solid	
			9	Contents of Packaged dosage Forms: Container Content	
			10	Assay (chemical)	
123.	281	Carboprost Tromethamine Injection Each ml contains Carboprost 0.25mg/ml	1	Description	
			2	Identification by IR	
			3	pH	
			4	Bacterial endotoxins	
			5	Particulate matter	
			6	Extractable volume	

			7	Assay by HPLC	
			8	Sterility (by MF)	
124.	284	Conjugated Estrogen Tablets USP 0.625 mg.	1	Description	
			2	Identification A (by GC)	
			3	Identification B (GC)	
			4	Average weight	
			5	Dissolution (By HPLC)	
				1st Stage	
				2nd stage	
				3rd Stage	
				4th Stage	
			6	Uniformity of content (byHPLC)	
			7	Contents of Packaged Dosage Forms	
			8	**Assay:** (by GC)	
125.	423	Hyaluronidase Injection IP Each vial contains Hyaluronidase IP 1500 I.U.	1	Description	
			2	Identification A (by Chemical)	
			3	Identification B (Performed on animals)	
			4	pH	
			5	Average Weight	
			6	Uniformity Of weight	
			7	Clarity of solution test a and b	
			8	Appearance of solution	
			9	Particulate matter	
			10	Bacterial endotoxins	
			11	**Assay:** Phenobarbital sodium (by UV)	
			12	Sterility	
126.	NE41	Ivermectine 12mg IP	1	Description	
			2	Identification (by HPLC)	
			3	Average Weight	
			4	Dissolution (by HPLC)	
			5	Uniformity of Content (by HPLC)	
			6	Limit of 8a-oxo-H2B1a	
			7	Contents of Packaged Dosage Forms	
			8	Assay (by HPLC)	
127.	NE39	Remedisivir Injection 100mg IP.	1	Description	
			2	Identification A (by HPLC)	
			3	Identification B (UV)	
			4	pH	
			5	Water	
			6	Average net Content	
			7	Related substances (by HPLC)	
			8	Uniformity Of weight	
			9	Clarity of solution test a and b	
			10	Appearance of solution	
			11	Particulate matter	
			12	Bacterial endotoxins	

			13	**Assay:** (by HPLC)	
			14	Sterility	
128.	NE47	Posaconazole Tablet 100mg	1	Description	
			2	Identification (by HPLC)	
			3	Average Weight	
			4	Disintegration or Dissolution (by HPLC)	
			5	Uniformity of Weight	
			6	Contents of Packaged Dosage Forms	
			7	Assay (by HPLC)	
129.	NE52	Injection Posaconazole 300mg	1	Description	
			2	Identification (by HPLC)	
			3	pH	
			4	Average net Content	
			5	Uniformity Of weight	
			6	Clarity of solution test a and b	
			7	Particulate matter	
			8	Bacterial endotoxins	
			9	**Assay:** (by HPLC)	
			10	Sterility	
130.	NE55	Baricitinib Tablet 2mg	1	Description	
			2	Identification (by HPLC)	
			3	Average Weight	
			4	Disintegration or Dissolution (by HPLC)	
			5	Uniformity of Content (by HPLC)	
			6	Contents of Packaged Dosage Forms	
			7	Assay (by HPLC)	
131.	NE56	Baricitinib Tablet 4mg	1	Description	
			2	Identification (by HPLC)	
			3	Average Weight	
			4	Disintegration or Dissolution (by HPLC)	
			5	Uniformity of Content (by HPLC)	
			6	Contents of Packaged Dosage Forms	
			7	Assay (by HPLC)	
132.	NE71	Posaconazole Oral Suspension	1	Description	
			2	Identification (by HPLC)	
			3	Water	
			4	pH	
			5	Stability of Suspension (by HPLC)	
			6	Contents of Packaged Dosage Forms	
			7	Assay (by HPLC)	
			8	Identification of colour	
			9	**Microbial Examination**	
				Total aerobic count	
				Total fungal count	
				E. coli	
133.	NE80	Molnupiravir Capsules	1	Description	

			2	Identification (by HPLC)	
			3	Average net content	
			4	Disintegration or Dissolution (by HPLC)	
			5	Uniformity of weight	
			6	Contents of Packaged Dosage Forms	
			7	Assay (by HPLC)	

ANNEXURE –VIII
Ref: Clause no. 3 (p)

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

A - General requirements and premises

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

B- Personal & Equipment

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

Chemicals and Reagents, Good housekeeping and safety

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

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

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

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

Quality system : & internal quality audits, management review :

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

Standard operating Procedures

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

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

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

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

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