

**Ref. No.:** F.02(382)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-11/2023/1441Dated :-25.07.2023

# 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@rajasthan.gov.in

## E-BID FOR THE RATE CONTRACT CUM EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS (Two Years RC ending on 30.09.2025)



!! सर्वे सन्तु निरामयाः!!

| LAST DATE OF SUBMISSION OF ONLINE BIDS            | 16.08.2023<br>&<br>6.00 PM  |
|---|-----------------------------|
| DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS | 17.08.2023<br>&<br>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 CIN:U24232RJ2011SGC035067 Website: www.rmsc.health.rajasthan.gov.in E-mail : edprmsc@rajasthan.gov.in

Ref. No.: F.02(382)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-11/2023/1441Dated :-25.07.2023

# **Notice Inviting E-Bids**

E-bids are invited up to 6.00 PM of 16.08.2023 from approved Drugs Testing Laboratories situated in India for analysis of Drugs. (Ending on **30.09.2025**).

Details of NIB may be seen at the website of State Public procurement Portal <u>http://sppp.rajasthan.nic.in</u>, http://eproc.rajasthan.gov.in., <u>http://rmsc.health.rajasthan.gov.in</u> and may be downloaded from there.

UBN.No

Executive Director (Procurement) RMSCL



# RAJASTHAN MEDICAL SERVICES CORPORATION LTD. RAJASTHAN

# e-BID FOR RATE CONTRACT CUM EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS

(Rate contract for two years ending on 30.09.2025)

| Bid Reference                                     | : | F.02(382)/RMSCL/ED (P)<br>EMPANELMENT/DTL/NIB-11/2023/1441Dated :-<br>25.07.2023 |
|---|---|--|
| Pre- bid conference                               | : | 28.07.2023at 12.30 P.M.  |
| Date and time for downloading bid document        | : | 25.07.2023from 06.00 PM  |
| Last date and time of submission of online bids   | : | 16.08.2023 at 6.00 PM  |
| Date and time of opening of Online technical bids | : | 17.08.2023 at 11.00 PM   |
| Cost of the Bid Document                          | : | Rs. 2360/- (Including GST@ 18%)  |
| <b>RISL Processing Fees</b>                       | : | Rs. 2950/- (Including GST @ 18%)   |
| Bid Security                                      | : | Rs. 20000/-  |



### RAJASTHAN MEDICAL SERVICES CORPORATION LTD. RAJASTHAN

## E-BID FOR RATE CONTRACT CUM EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS (Rate contract for two years ending on 30.09.2025)

## "CONFIDENTIALITY IS THE ESSENCE OF THIS BID" 1. LAST DATE FOR RECEIPT OF BIDS, BID FORM FEES, BID SECURITY & RISL PROCESSING FEES

- a) E-Bids [In Two Separate Bids (Technical Bid & Price Bid)] Shall Be Received Till 06.00 PM on 16.08.2023 By The Rajasthan Medical Services Corporation Ltd, For The Rate contract cum Empanelment Of Analytical Testing Laboratories For The Test And Analysis Of DRUGS (Rate contract for two years ending on 30.09.2025) 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 Bid Security 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 i.e. http://eproc.rajasthan.gov.in. Every Bidder will be required to pay the Bid form fee Rs. 2360/- (Including GST@ 18%) for downloaded forms from the website, Bid Security as applicable in Bid condition no. 6 and processing fee of Rs. 2950/- (Including GST@ 18%) of R.I.S.L. through three separate prescribed challans (*format enclosed in Annexure- I*) in any branch of the Punjab National Bank into Account no. 2246002100024414 throughout the country upto 16.08.2023 or through D.D. / Bankers Cheque in favour of M.D. RMSCL (tender fees and Bid Security) and MD, RISL ( tender processing fees) physically in the office of RMSCL by 6.00 PM on 16.08.2023 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, processing fees and Bid Security. In the absence of Bid fees, processing fees and Bid Security the Bids shall be rejected and shall not be opened.



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

- (1) Drug Testing Laboratories should have valid Approval for carrying out test on drugs under the Drugs and Cosmetics Act, 1940 and Rules there under. Three years standing in the test & analysis of **drug items** and the lab shall be entitled for empanelment for the categories of items for which lab has bidded and having approval. Bid is invited from approved Drugs Testing Laboratories situated in India.
- (2) The laboratory should be GLP compliant under the provisions of Drugs and Cosmetics Act, 1940 and Rules there under and should hold schedule L-1 certificate or should have approval from Drug Control Department and NABL accreditation with proper scope of accreditation to undertake testing of drug items.
- (3) The laboratory should have an average annual turnover of not less than Rs.
  50 Lakh for past preceding three years (2019-20, 2020-21 & 2021-22 or 2020-21, 2021-22 & 2022-23).

Only audited accounts would be considered provisional accounts would not be considered in any case.

- (4) The lab should have undertaken test and analysis of drugs and supplies of similar nature of drugs for 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 or its Organizations or its 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.

- Bidders are allowed the option to quote for anyone item or more items as mentioned in bid (list of medicines proposed to be analyzed tested as at Annexure-VII).
- b. The bidders shall submit/upload in Technical Bid scanned copies of all the challans / DD/ BC of deposits of Bid form fees, RISL processing fee and Bid Security Money.
- 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 <u>Drug and medical items</u> for 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 31.12.2022 or latest Months.
- h. Non- Conviction Certificate by the State Licensing Authority/ competent authority.
- Annual turnover statement for 3 year i.e. (2019-20, 2020-21 & 2021-22 or 2020-21, 2021-22 & 2022-23) certified by the practicing Chartered Accountant with UDIN No.
- j. Copies of the Balance Sheet and Profit and Loss Account for three years i.e. (2019-20, 2020-21 & 2021-22 or 2020-21, 2021-22 & 2022-23) duly audited or certified by the practicing Chartered Accountant. No provisional balance sheet or Profit and Loss account would be entertained.
- 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.
  - 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 the Standard Quality".
- 1. 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 uploaded on e-Proc site and will be part of the 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 shall 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 bid is liable to be rejected for the particular item. 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 clarifications on prices or rebates shall not be accepted.

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

The technical bids would be opened on scheduled date and time on eproc website i.e. <u>https://eproc.rajasthan.gov.in</u>. After technical evaluation physical inspection of the laboratories may be carried out by the designated team. Thereafter financial bids would be opened of those bidders who are found finally responsive on technical criteria. The acceptable rates for analysis will be decided and communicated accordingly.



The Bid Security Money Deposit shall be Rs. 20,000/- (Rs Twenty Thousand only) 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 16.08.2023 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSC by 6.00 PM on 16.08.2023 Bid Security Deposit in any other form will not be accepted

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

Government undertaking PSU are exempted from Bid Security 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. However wherever rates for individual test are demanded, they should be furnished accordingly in BOQ.
- 3. The rates quoted should be exclusive of taxes, though the applicable taxes are to be mentioned separately.
- 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 rate contract period including extensions, if any given.
- 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 to any other laboratory.
- 7. RMSCL shall have the right to cause inspection of the laboratory 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.
- 9. GST at applicable rate should be mentioned by the bidder where evere applicable.



#### 8. ACCEPTANCE OF BID

- The Bid evaluation committee formed by Managing Director, Rajasthan Medical Services Corporation Ltd. will evaluate the Bid with reference to various criteria specified in bid document.
- 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 bids depending on the volume of analytical work.

#### 9. AGREEMENT

- 1. The agreement with empanelled laboratories shall remain valid up to 30.09.2025. If Required period of contract can be extended upto 3 months on same rate, terms and condition without any prior consent of the bidder 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. (Annexure IX)
- **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 other 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 emailed on its email address or left at the premises, places of business or abode.

### 10. PERFORMANCE SECURITY

The successful Bidders shall be required to pay a Performance Security of Rs.
 50,000/- (Rs Fifty Thousand only) *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) Mentioning only "COMPLIES" or "PASSES" in the result column of the report would be 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.

- 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 (Quality immediately to the E.D. 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.
- 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.
- 4. GST shall be applicable as per prevailing rates notified by the Government.

#### **13. PENALTIES**

- 1. If the successful Bidder fails to execute the agreement and deposit security within the time amount specified or withdraws the BID after intimation of the acceptance of the BID or owing to any other reasons, is unable to undertake the contract, the empanelment will be cancelled and the Earnest Money amount 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 breach of BID conditions. Such damages shall be assessed by the Managing Director, Rajasthan Medical Services Corporation Limited whose decision shall be final and binding.
- 2. After entering into Rate contract, if the laboratory does not as per the terms and conditions, it may be disqualified 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, the empanelment of any laboratory either wholly or in part at one month's notice without assigning any reasons. 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 it 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. <u>CORRECTION OF ARITHMETIC ERRORS:</u>

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. <u>GRIEVANCE REDRESSAL DURING EMPANELMENT PROCESS:</u>

The Designation and address of the First Appellate Authority is MD, NRHM.

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

#### 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</u> CONFLICT OF INTEREST:

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. JURISDICTION

 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.+

### **19.** <u>APPLICABILITY OF RULES</u>

Besides above conditions all the provisions of RTPP Act 2012 & RTPP Rules 2013 shall be applicable.

Managing Director Rajasthan Medical Services Corporation



| Acknowledgement Cashier/Officer                               | Cashier/Officer  | Acknowledgement           |
|---|--|---------------------------|
| For Bank use only   | For Bank use only  |                           |
| Address for communication                                     | unication  | Address for communication |
| Signature   |  | Signature                 |
| Name of the Depositor   | sitor  | Name of the Depositor     |
|   |  | Amount (in words): <      |
| A mount (in worde), 2   |  | Total                     |
| Total   |  | Coins *                   |
| Total amount ₹  |  | \$<br>*                   |
| Commission ₹ 0 0 0 0 0  |  | 10 *                      |
|   |  | 30 *                      |
| 50 *  |  | 100 *                     |
| 100 *   |  | 500 *                     |
| 1000 *  | 45-54  | 1000 *                    |
| ₹ Ps  | ₹ Ps Chq No Date of Chq Name of Bank ₹ Ps                  | Lomination                |
| Cash Deposit: Cheque Deposit:                                 | Checue Denosit:  | had Dependent.            |
| Mobile No.  |  | Mobile No.                |
| Type of Deposit [lecs/Others]<br>[lecs/Others]                | Type of Deposit fees/Others                                | Type of Deposi            |
| Tender Ref. No.   |  | Tender Ref. No.           |
| Supplier Name   |  | Supplier Name             |
| DETAILS OF THE SUPPLIER                                       |  | DETAILS OF THE SUPPLIER   |
| DD MM YY  |  |                           |
| Date of Deposit   |  | Institute 10              |
| Institute ID RMSCJ - A/c No. 2246002100024414                 | RMSCJ - A/c No. 2246002100024414                           |                           |
| Institute Name Rajasthan Medical Services Corporation, Jaipur | Rajasthan Medical Services Corporation, Jaipur             | Institute Name            |
| T   |  | Branch                    |
| punjab national bank DIST. NO.                                | punjab national bank DIST. NO.                             | See                       |
|   | Bank Copy  |                           |
|   | AUTION : USE "FCMBR" MENU OF HUN IN FUNACLE HISTERY OF ANY | LION : USE                |



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

**3(h)** 

## ANNUAL TURN OVER STATEMENT

| T         | he Annual                         |                | Turnover            | of        |
|-----------|-----------------------------------|----------------|---------------------|-----------|
| M/s       |                                   |                | for the past three  | years are |
| given bel | ow and certified that the stateme | ent is true an | d correct.          |           |
| S.No.     | Years                             |                | Turnover in Lacs (1 | Rs)       |
| 1         | 2019-20                           |                |                     |           |
| 2         | 2020-21                           |                |                     |           |
| 3         | 2021-22                           |                |                     |           |
|           | Total                             | Rs.            |                     | Lacs      |
| Ave       | erage turnover per annual         | Rs.            |                     | Lacs      |
|           |                                   | Or             |                     |           |
| S.No.     | Years                             |                | Turnover in Lacs () | Rs)       |
| 1         | 2020-21                           |                |                     |           |
| 2         | 2021-22                           |                |                     |           |
| 3         | 2022-23                           |                |                     |           |
|           | Total                             | Rs.            |                     | Lacs      |
| Ave       | erage turnover per annual         | Rs.            |                     | Lacs      |

Date:

Siganture of Auditor/ Chartered Accountant

Seal: UDIN No.

(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 Sam   | ples Analysed         | No. of Samples | Analysed during                            |
|                | (2019-20,             | 2020-21 & 2021 | -22 or 2020-21, 2021-22 & 2022-23          |
| 01. Tablets /  | Capsules / Pessaries/ | Dry Powders    |  |
| 02. Injectable | S                     |                |  |
| 03. Liquid Pr  | eparations            |                |  |
| 04. Ointment   | s / Creams / Gels     |                |  |
| 05. Others (S  | pecify)               |                |  |
| 06. Surgicals  | (Specify item name    | s)             |  |
| 07. Sutures (S | Specify types)        |                |  |
| 08. Implants   |                       |                |  |
| 09. Devices    |                       |                |  |
|                |                       |                | Signature :<br>Date :<br>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 drug items)

Signature :

Date :

Nam e of the Lab :

Office Seal :



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

| S.No.   | Name of the Equipme     | nt Make &   | Date of                         | Date of                         |
|---------|-------------------------|-------------|---------------------------------|---------------------------------|
| Appro   | ved                     |             |                                 |                                 |
|         | Instruments / Apparatus | Description | Installation last<br>Validation | for testing<br>of drugs<br>from |
| State   |                         |             |                                 |                                 |
| licensi | ng                      |             |                                 |                                 |

U

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, r              | esident of      | , am        |
|----|--|-----------------------|-----------------|-------------|
|    | proprietor /Partner/Director                   | having                | our             | office      |
|    | at   | and the approved      | drug testing    | laboratory  |
|    | at   | do hereby decla       | are that I have | e carefully |
|    | read all the conditions of BID of Ra           | ajasthan Medical Se   | ervices Corpor  | ation Ltd., |
|    | Jaipur, for the BIDs floated for               | empanelment of        | approved dru    | gs testing  |
|    | laboratories for analysis of drugs.            | (Rate contract f      | or two years    | ending on   |
|    | <b>30.09.2025</b> ) and shall abide by all the | he conditions set for | rth therein.    |             |
|    |  |                       |                 |             |

- I further declare that I possess valid approval for testing of all the drug items 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.
- That the approval to test drug items 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(382)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-11/2023/ Dated :-

6. That we have testing facilities as per testing parameters mentioned in respective pharmacopoeias (IP/BP/USP etc.) and quoted for products as given below:-

| Sr No. | Quoted item Code No. (as per mention<br>in Annexure-VII) |
|--------|--|
| 1.     | For Example 2  |
| 2.     |  |
| 3.     |  |

- 7. For the empanelment of analytical testing laboratories for the test and analysis of DRUGS (Rate contract for two years ending on **30.09.2025**) for Rajasthan medical services corporation and accept all conditions of bid, including amendments if any.
- 8. 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;
- 9. Our complete address for communication with phone no.:- -----



| 10. | E mail address :              |
|-----|-------------------------------|
| 11. | Bank detail for e banking :-  |
|     | Name of account holder        |
|     | Full name of Bank with Branch |
|     | A/c no. with full digits      |
|     | IFSC code                     |
|     |                               |

(Deponent)

Signature :

Date :

Name of the Lab : Office Seal :

#### **Verification**

I.....S/o.....(Designation)..... Affirm on oath that the contents/information from para 1 to 11 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

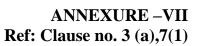
(Name of Deponent & Signature)

ATTESTED BY NOTARY PUBLIC



## **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 et   | C.    |
| 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 (G or  | LP) : |
| 9.  | <ul><li>(i) NABL Accreditation no. &amp; date</li><li>(ii) Scope of Accreditation</li><li>(iii) Its validity.</li></ul> |       |
| 10. | Name of the authorized signatory :  |       |
| 11. | Specimen Signature of the authorized<br>Signatory   | :     |
| 12. | Names & Specimen Signatures of the<br>Approved technical Staff who are authorized<br>to sign the test reports           | :     |



## NOTE:-

• Bidders have to mention quoted item code in annexure V for which have testing facility as per respective pharmacopoeias (IP/BP/USP etc).

| S.<br>No. | Code No. | Name of item with specification   |
|-----------|----------|---|
| 1<br>1    | 2        | 3   |
| 1.        | NRD-186  | Inj. Ceftriaxone 1000 mg + Sulbactam 500 mg IP (Each Vial Contains:Ceftriaxone 1000   |
|           | 100      | mg + Sulbactam 500 mg with Sterilised Water for Injections, 10 ml)  |
| 2.        | NRD-188  | Inj. Cefuroxime Sodium 1gm IP (each vial contains Cefuroxime Sodium 1gm)  |
| 3.        | NRD-233  | Fentanyl Transdermal patch 25 mcg/hour (Each patch deliver Fentanyl 25 mcg/hour)  |
| 4.        | NRD-234  | Fentanyl Transdermal patch 50 mcg/hour (Each patch deliver Fentanyl 50 mcg/hour)  |
| 5.        | NRD-241  | Inj. Folic Acid. Cynocobalamine and Nicotinamide Inj (Each ml contains Folic Acid 200   |
|           |          | mcg. Cynocobalamine 5 mcg and Nicotinamide 20 mg) in 10 ml.   |
| 6.        | NRD-259  | Mefenamic acid 250mg+ dicyclomine hydrochloride10mg Each Tablet contain Mefenamic acid 250mg+ dicyclomine hydrochloride10mg   |
| 7.        | NRD-261  | Inj. Insulin Lispro Inj. 3 ml in 100IU/ml IP (Each ml contains Insulin Lispro 100IU/ ml in 3 ml Pre-filled Pen)   |
| 8.        | NRD-275  | Inj. Lignocaine IP (preservative free) (Each ml contains Lignocaine IP 21.3 mg sodium chloride IP 6.0 mg 50 ml vial)  |
| 9.        | NRD-284  | Enoxaparin Sodium Injection(Low Molecular Wt. Heparin) 40mg/ 0.4mg IP   |
| 10.       | NRD-288  | Inj. Methotrexate 250 mg IP (each ml contain Methotrexate 25 mg in 10ml vial)   |
| 11.       | NRD-292  | Inj. Methylprednisolone Acetate 125 mg I.P. (Each vial contains Methylprednisolone Acetate 125 mg)  |
| 12.       | NRD-293  | Inj. Metotrexate 15mg/ml IP (Each ml contains Metotrexate 15mg)   |
| 13.       | NRD-315  | Inj. Sodium Chloride 0.9% 500 ml Glass Bottle Inj. IP   |
| 14.       | NRD-316  | Inj. Sodium Chloride 0.9% 1000 ml Glass Bottle Inj. IP  |
| 15.       | NRD-324  | Inj. Paracetamol infusion 500 mg with both Temper evident caps IP ( Each 100 ml contains Paracetamol 500 mg )   |
| 16.       | NRD-362  | Inj. Ropivacaine 0.75% 20 ml Ampule/vial (Each ml contains: Ropivacaine 7.5 mg/ 0.75% in 20 ml Amoule)  |
| 17.       | NRD-369  | Inj. Streptomycin Injection 500mg/ vial IP (Each Vial Contains: Streptomycin 500 mg)  |
| 18.       | NRD-414  | Lotion Minoxidil 5% W/V in 60ml   |
| 19.       | NRD-424  | MDI Formoterol 6 mcg. + Budesonide 400 mcg IP ( Each Actuation deliver Formoterol 6 mcg &Budesonide 400 mcg)  |
| 20.       | NRD-438  | Ointment Neomycin, Polymyxin B and Bacitracin Zinc Ophthalmic 5 gm IP (Each gram contains polymyxin B sulfate usp 5000 units, Bacitracin 400 units ,Neomycin sulphate and Zinc Oxide in Ointment base ) |
| 21.       | NRD-444  | Paint Mercunium Chloride 10ml   |
| 22.       | NRD-534  | Tab. 6-Mercaptopurine 20 mg I.P.  |
| 23.       | NRD-608  | Tab. Diltiazem CR/Prolonged Released Tablet 90 mg BP (Each capsule/ tablet contains Diltiazem 450 mg)   |
| 24.       | NRD-677  | Tab. Methimazole 5 mg USP(Each tablet contains Methimazole 5 mg)  |
| 25.       | NRD-762  | Tab. Rifampicin 450 mg IP (Each capsule/ tablet contains Rifampicin IP 450 mg)  |
| 26.       | NRD-763  | Tab. Rifampicin 600 mg IP (Each capsule/ tablet contains Rifampicin IP 600 mg)  |
| 27.       | NRD-811  | Tab. Verapamil Hydrochloride Sustained Release 120 mg IP (Each tablet contains 120 mg SR of verapamil hydrochloride)  |
| 28.       | NRD-899  | Tab. Nicotine 2 mg  |
| 29.       | NRD-900  | Tab. Nicotine 4 mg  |
| 30.       | NRD-901  | Dapagliflozin 5 mg  |
| 31.       | NRD-902  | Chlorthalidone 12.5 mg IP   |
| 32.       | NRD-903  | Chlorthalidone 25 mg IP   |
| 33.       | 368      | Cough Syrup<br>Each 5ml contains Chloropheniramine Maleate IP 3mg Ammonium Chloride 130mg,<br>Sodium Citrate 65 mg with flavoured syrup base containing menthol.] in 50ml bottle with<br>measuring cap. |
| 34.       | 692      | Cough Syrup/ Expectorant<br>Each 5ml contains Ambroxol 15mg, Terbutaline Sulphate IP 1.5mg, Guaiphenesin IP 50mg,<br>with flavoured syrup base containing menthol.] in 50ml bottle with measuring cap.  |
| 35.       | NE-75    | Morphine Sulphate 30 mg SR Tablet   |



## ANNEXURE –VIII Ref: Clause no. 3 (p)

# <u>To fill up the remark column of the enclosed Performa to access the</u> <u>existing facilities of your laboratories</u>

## 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 :

|      | Details of the requirement   | Remark |
|------|--|--------|
| S.N. |  |        |
| 1    | All equipments, instruments and other devices used in the laboratory shall use<br>appropriate methods and procedures for all tests or calibrations and they shall<br>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    |        |



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



| 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:



## ANNEXURE –IX Ref: Clause no. 9 (2)

#### AGREEMENT

This Deed Agreement made this of is on dav 2023 represented by its of by M/s. Proprietor/ /Managing Director having its laboratory Premises Managing partner at (hereinafter referred to as "Service provider" which term shall include its successors, representatives, heirs, executors and administrators unless excluded by the Contract) on one part and Rajasthan Medical Services Corporation Ltd, represented by its Executive Director (P) having is office at Swasthya Bhawan, Tilak Marg, C-Scheme, Jaipur (hereinafter referred to as "The Purchaser" which term shall include its successors, representatives, executors assigns and administrator unless excluded by the Contract) on the other part.

Whereas the Service provider has agreed to test the Drugs and Medicines for RMSC with specifications mentioned in the Schedule attached here to and mentioned at the prices noted there

in and in the manner and under the terms and conditions here in after mentioned and where as the Service provider has deposited with the Purchaser а sum of Rs (Rupees only) as Performance Security Deposit for the due and faithful performance of this Agreement, to be forfeited in the event of the Service provider failing duly and faithfully to perform it. Now these presents witness that for carrying duly and faithfully to perform it. Now these presents witness that for carrying out the said Agreement in this behalf into execution the Service provider and the Purchaser do hereby mutually covenant, declare, contract and agree each of them with the other of them in the manner following, that is to say.

The term "Agreement", wherever used in this connection, shall mean and include the terms and conditions including amendments contained in the invitation to tender floated for the Empanelment of Analytical Testing Laboratories for the test and Analysis of Drugs for Rajasthan Medical Services Corporation Ltd F.02(382)/RMSCL/ED (P) EMPANELMENT/DTL/NIB-11/2023/1441Dated :- 25.07.2023 the instruction to Bidders, the conditions of Bid, acceptance of Bid, particulars hereinafter defined and those general and special conditions that may be added from time to time.

1. (a) The Agreement is for the test by the Service provider to the Purchaser of the testing of Drug and Medicines specified in the Schedule attached here to at process noted against each therein on the terms and conditions set forth in the Agreement.

(b) This Agreement shall be deemed to have come into force with effect from the date of issuance of letter of acceptance no. .....and dated.....and it shall remain in force up to 30.09.2025 and extendable upto 3 months, if required. Firm shall be bound to accept the extension period of Rate Contract.

#### **TERMINATION OF CONTRACT ON BREACH OF CONDITION**

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

(b) In case the Service provider fails, neglects, or refuse to observe, perform, fulfill and keep, all or any one or more or any part of any one of the Covenants, stipulation and provisions herein contained, it shall be lawful for the Purchaser on any such failure, neglect or refusal, to put an end to this Agreement and thereupon every article, cause and thing herein contained on the part of the Purchaser shall cease and be void, and in case of any damage, loss, expenses, difference in cost or other moneys from out of any moneys for the time being payable to the Service provider under this and/or any other Contract and in case such last mentioned moneys are insufficient to cover all such damages, losses, expenses, difference in cost and other moneys as aforesaid, it shall be lawful for the Purchaser to appropriate the Performance Security made by the Service provider as herein before mentioned to reimburse all such damages, losses, expenses, difference in cost and other money as the Purchaser shall have sustained, incurred or been put to by reason of the



Service provider having been guilty of any such failure, negligence or refusal as aforesaid or other breach in the performance of this Contract.

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

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

#### **NOTICE ETC, IN WRITING**

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

#### <u>SERVICE PROVIDER NOT HAVE ANY INTEREST IN THE OFFICERS CONCERNED AND</u> <u>SUBORDINATES</u>

4. The Service provider shall not be in any way interested in or concerned directly or indirectly with, any of the Officers, Subordinate or Servants of the Purchaser. In any trade, business or transactions nor shall the Service provider give or pay or promise to give or pay any such Officer, Subordinate or Servant directly or indirectly any money or fee or other consideration under designation of "Custom" or otherwise; nor shall the Service provider permit any person or persons whomsoever to interfere in the management or performance hereof under power of attorney or otherwise without the consent in writing the consent in writing of the Purchaser obtained in first hand.

#### **BANKRUPTCY OF THE SERVICE PROVIDER**

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

#### SERVING OF NOTICE ON SERVICE PROVIDER

- 6. All notice or communication relating to or arising out of this Agreement or any of the terms thereof shall be considered duly served on or given to the Service provider if delivered to him or left at his premises, place of business or abode.
- 7. And it is hereby agreed and declared between the parties hereto that in case any question of dispute arises touching the construction or wording of any of clause herein contained on the rights, duties, liabilities of the parties hereto or any other way, touching or arising out of the presents, the decision of the Managing Director, Rajasthan Medical Services Corporation Ltd in the matter shall be final and binding.
- 8. All disputes arising out of this agreement and all questions relating to the interpretation of this agreement shall be decide by the Govt. and the decision of the Govt. shall be final.

#### SERVICER PROVIDER (Signature, Name & Full Address)

Executive Director (Procurement), RAJASTHAN MEDICALSERVICES CORPORATION LTD.

Witness (Signature, Name & Full Address) 1.

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