QUALITY CONTROL
POLICY & PROCEDURES
OF RMSC

01. Introduction:

Rajasthan Medical Service Corporation Limited is a Public Undertaking of Govt. of Rajasthan which will act as nodal agency for procurement of drugs, medicines, surgical & sutures to various Government Institutions in the state. It shall procure the items in generic names as per prescribed standards by finalizing the rates and supplies through open tender process as per Rules.

The drugs, medicines, surgicals & sutures shall be procured, based on the need and consumption pattern of the items by the medical institutions. Procurement orders are proposed to be placed to meet out 4 months need and 2 months pipeline stock likely to be in transit and under quarantine. Though the procurement will be centralized but the suppliers will be required to supply the items directly (F.O.R.) to the District Drugs Warehouses (DDW) as per instructions.

The stock of drugs received in DDW will be entered in stock register and kept in quarantine till sampling and receipt of test reports.

02. Tender Process for Empanelment of Laboratories:

2.1 Approved Drugs Testing Laboratories of Rajasthan and other nearby states where samples can be sent within a day time will be considered for empanelment through limited / open tender system.

The documents to be demanded for empanelment will include:-

I. Approval on form 37 issued by State Licensing Authority.
II. Renewal on form 38 issued by State Licensing Authority, if necessary.
III. Categories of drugs approved for the testing.
IV. Documentary evidence of having analysed Drugs /Surgical / Sutures for the last 3 years
V. Compliance to Schedule L-1 of Drugs & Cosmetics Rules, 1945.
VI. List of Equipments along with their specifications.
VII. List of technical staff along with their qualification & experience. Approved & Non-approved.
VIII. Non-Conviction Certificate issued by State Licensing Authority.

IX. Total numbers of samples tested category wise in last three years. (Year-wise)
X. Balance Sheet of last three years.
XI. Product wise rates of testing charges.
XII. Accreditation / Certification, if any.
XIII. Any other conditions which may be specified by the RMSC.

2.2 Rates for testing and analysis of the drugs, medicines, surgical & sutures will be fixed by tender process by RMSC and successful Testing Laboratories will be empanelled with the corporation every year.

2.3 The other bidders will be requested to match the L-1 bidder's rate. Based on these criteria the list of labs for each item will be prepared.

2.4 The successful tenderers shall be required to pay a security deposit, as may be prescribed from time to time at the time of execution of agreement. At present security deposit is Rs. 25,000/-

2.5 Average turnover limit per annum of Rs. 25 Lakhs for the preceding 3 years will be one of the eligibility criteria.

2.6 Government Laboratories, Research & Development Laboratories, Laboratories run by Co-operative body & Educational Institutions are exempted from the turnover criteria

2.7 The Corporation may decide to carry out inspection of the laboratories by team of expert's viz. Assistant Drugs Controller, Assistant Govt. Analyst and Quality Control Officials of RMSC which may be decided from time to time by the Corporation to assess GLP compliance and capacity to undertake the testing work.

03. Procedure for Receipt of stock & Drawl of Samples from District Drug Warehouses:

3.1 Stock of medicines received will be entered by the warehouse in-charge in Register as well as in computer.

3.2 Stock of medicines will be kept in QUARANTINE AREA.

3.3 Head office will immediately be informed about receipt of stock.

3.4 Each and every batch of drugs /medicines supplied by the suppliers shall be subjected to quality test by the laboratories empanelled through open tender process.

3.5 Samples will be drawn in three times the quantity of the item required for testing from each batch of supply from the warehouses by the team of ware house incharge, pharmacist and other members who may be notified on day to day basis as per sampling plan which will be communicated from head office. The item wise sampling quantity to be drawn will be provided from head office to all DDW's.

3.6 The samples drawn in warehouses will be duly packed; sealed and outer packing duly signed by members of the team and will be sent along with requisition slip to the Head Office of RMSC through the courier to reach the next day at Jaipur. Information in respect of despatch will be given telephonically and through mail / fax to the head office.

3.7 If any batch of the particular product received after 5 days in any another warehouse of RMSC then the sample may again be drawn from received stock and be sent for analysis once again. In this case the outer packing of sample & requisition slip will bear the remark as "Re-sampled - Same batch received after ..... days gap" so that the head office may identify for getting it tested from another laboratory.

3.8 In order to ensure the quality of the drugs during the storage period also, RMSC may draw and analyse the drug samples which may be lying in the warehouse for more than 6 months to counter check the stability and quality of the drugs during storage period.

3.9 In case of specific complaint or any suspicion about the quality, the Inspection team of Officers of RMSC will be constituted and / or an officer going for inspection of the warehouse may also randomly select the drug and take samples and the same will be handed over to the Quality Control section, Head office for analysis and outcome of the report will have to be reported to the Managing Director immediately.

4. Process Adopted for sample Analysis:

4.1 From the samples received in the Head office from all the warehouses, the quantity of common batch of each item will be mixed and Samples will be taken on random basis. Three sample portions of each batch, each containing minimum required quantity will be segregated.

4.2 The particulars like manufacturers name, batch no, Mfg. Date, Exp. Date, Mfg Lic. No. etc of drug of one sample portion will be concealed either by using black indelible ink marker pen or the tablets and capsules will be removed from the strips and blisters; and labels of those of vials, ampoules and bottles will be removed and thereafter sample portions be properly assigned code with secret number. Remaining two portions will

be kept in original packing but duly packed and similar secret code numbers will be assigned on them and kept in the office. All relevant entries will be made in register and portion meant for testing will be sent to different Empanelled Laboratories for analysis as per plan. Requisition slip to accompany with the sample will bear name, specification and strength of drug and secret code number only.

4.3 Samples of formulations containing hygroscopic / deliquescent drug substances, such as Ranitidine, Sodium Valporate Tablets etc. will be sent to the Empanelled Laboratories as such after removing the names of suppliers, batch nos. etc. from the strips.

4.4 The secret code number will be system generated and selection of laboratories for analysis will be kept confidential and it will be decided by the higher level officers based on the performance and backlog with the labs.

4.5 Locally samples will be sent through messenger and outside city they will be sent through courier to ensure that it reaches the labs, the next day.

5. Salient points applicable for the Analysis by the Empanelled Laboratories:

5.1 All the tests mentioned in IP/BP/USP/Drugs & Cosmetics Act. etc., (as the case may be) should be carried out for each and every sample. The results obtained in the test should be mentioned in figure (wherever possible).

5.2 "COMPLIES" or "PASSES" in the result column of the report is treated as incomplete report, if the result has some value and same is not reported.

5.3 Every test report must have remarks (i.e.) Standard Quality or Not of Standard Quality.

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

5.5 Reports should have S.No., Code No., Test Protocol, Description of tests, Specifications & Results of test and analysis.

5.6 Reports should be attached along with Spectra/Chromatography data sheets if applicable.

5.7 Report should be uploaded on the website of RMSC and simultaneously be E-Mailed to head office, RMSC apart from sending it by fax/mail.

6. Time Line for Analysing and Furnishing Report:

6.1 On empanelment and entrustment of the job, the Analytical Laboratory should furnish the test reports within:

I. 10 days of receipt of the sample in case of Tablets, Capsules, Pessaries, Ointments, Powder and Liquid Oral Preparations.

II. 21 days of receipt of the sample in the case of I.V. Fluids and Injections.

III. Within 24hrs of the receipt of the samples, the information in appropriate format should be uploaded to the RMSC website in addition to confirmation by fax/mail.

6.2 All test reports should be submitted by the labs in triplicate. In case of failure of sample, the result should be communicated to the RMSC through phone/fax/e-mail and all the reports should be sent with protocols. All the reports should be signed by authorized approved Technical Person.

6.3 If due to any reason like breakdown of the instrument, non-availability of the reference samples etc., the analytical laboratory is unable to under take analysis of the sample, the same should be reported within 24 hours by fax/e-mail and the sample should be returned to the RMSC.

7. Acceptance Criteria and Retrieval Mechanism:

7.1 If such sample passes quality test in all respects, the results will be up-dated to the warehouses through email and RMSC will instruct its Warehouses to issue such items of drugs to various Government hospitals/Institutions.

7.2 Any sample sent to the Empanelled laboratories, if fails in specified quality parameters, the results will be confirmed from the other Empanelled laboratories / Government Analyst by sending second portion of sample portion before taking final decision.

7.2 A [4*] In cases of inconsistency /contradiction of test report received from first empanelled lab and second empanelled lab, for the drugs, failed in quality parameter or declared NOSQ, than sample of such drugs be send to government lab (DTL) for confirmation of test report before taking final decision.

7.3 If the drug fails in ASSAY or any other parameters, immediately letters will be issued to the warehouses to freeze the stock and ask them to remove from the main stock and kept separately until it is cleared by the Quality Control department. If the Empanelled Laboratories/Government Analyst

confirms the failure of the drug supplied by the supplier, the stocks will be returned to the supplier under intimation to the Drugs Controller. After 30 days of the letter for return of stocks, if the stocks are not taken by the Supplier and lying in the warehouses, penalty of 2% per week will be levied on the value of stocks lying in the warehouse till it is destroyed by RMSC (90 days).

7.4 In case of any failure reported by the Government Analyst on the samples drawn by the Drug Control Officer from the Storage points (hospitals) immediately a letter will be communicated to the Warehouse in-charges to stop the issue of the product and also request them to retrieve the drug supplied to the hospitals.

7.5 The Warehouse in-charge will in turn issue letters to each and every Institution where the batch has been supplied for retrieval of the drugs and request hospitals to collect the stocks from the wards and sub stores and inform the Warehouse in-charge about the quantity available over phone and through registered letters and send back the stocks within two days from the date of receipt of the letter.

7.6 The total value of the failed batch will be deducted from the bills of supplier and depending on the nature of failures of the product, the product / Company will be examined to consider banning and / or blacklisting after following due procedures.

7.7 The Drugs Control Department will also be requested by RMSC in case of any Not of Standard Quality report of any drug, on the sample drawn from the Hospital / Institution by the Drugs Control Officer, additional samples of the same drug (different Batch Nos.) may be drawn (or) other drugs supplied by the same company from different locations in the State, to verify the quality of the drugs.

7.8 RMSC will also take steps to verify the cumulative ASSAY value of each drug so as to keep watch on the supplier that they are keeping the strength of the drug on the upper limits. In case of consistent lower Assay value the QC Head may call for BMR of specific batch nos., purchase invoice and test protocols of API used in manufacture of batch.

8. Vaccines & Serums :

8.1 The supply of vaccines and serums are allowed to be distributed to the hospitals as per the clearance test report of CRI, Kausuli. In addition to this, samples of the Vaccines will be drawn from the warehouses randomly and

sent to the laboratories for analysis notwithstanding the fact that they might be previously got tested by the manufacturer from the CRI, Kasauli.

8.2 In case of any adverse reactions reported in the Hospitals during administration of any Vaccines, Serums or any Injectables, the Warehouse in-charges will be requested to act immediately and to inform the same to the Head Office over phone as well as in writing and freeze the drug and retrieve all the stocks from the Hospitals.

8A [1*] Testing of (1.) Surgicals & Sutures and (2.) Biological products & Blood Grouping Reagents.

Surgicals, Sutures, Biological products & Blood grouping reagents categories of drugs shall be tested on random basis that should not be less than 10 % of the batches supplied. Sterile products will be tested for sterility and Bacterial Endo toxin test (wherever prescribed) from empanelled labs. These items will be released for distribution on the basis of manufacturer's QC passed test report.

9. Payments:

9.1 No advance payment towards any analysis will be made to the empanelled tenderer.

9.2 No payment will be made for the incomplete analysis or incomplete report.

9.3 Payments towards the analysis of Drugs, Surgicals and Sutures will be made along with Tax at the prevailing rate as applicable at the time of payment strictly as per rules of the RMSC

10. Penalties:

10.1 [2*] For any delay more than stipulated in para a 6.1 (I) & a (II) as the case may be, liquidated damages will be charged as per following schedule:-

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

10.2 [3*] The liquidated damages for incomplete testing of samples will not be less than 10% and exceed depending on the nature and critical aspect of leftover test. However this condition will not apply when corporation consent or asked to carry out certain specific test only.

11. Blacklisting Procedures on Quality Failure:

11.1 If the successful tenderer fails to execute the agreement and payment of security deposit within the time specified or withdraws the tender after intimation of the acceptance of the tender 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 deposited by the tenderer shall stand forfeited to the RMSC. Such tenderer(s) will also be liable for all damages sustained by the RMSC by reasons of breach of tender conditions. Such damages shall be assessed by the Managing Director, RMSC whose decision shall be final.

11.2 Non-performance of any tenderer or violations of empanelment conditions will disqualify a laboratory to participate in the tender for a period as decided by RMSC.

11.3 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 the 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.

11.4 If it is revealed that the empanelled analytical Laboratory is involved in any form of fraud and collusion with the suppliers of RMSC, the Analytical Laboratory will be blacklisted. The tenderers shall also be liable for action under criminal law and blacklisting. The matter will also be notified to the concerned State Drugs Controller for suitable action against them.

11.5 The Managing Director, RMSC 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 tenderer will not be entitled for any compensation whatsoever in respect of such termination.

12. Resolution of Disputes

12.1 In all matters pertaining to the tender, the decision of the Managing Director, RMSC shall be final and binding.

12.2 In the event of any dispute arising out of the tender such dispute would be subject to the jurisdiction of the civil courts within the city of Jaipur.

[1*] Added w.e.f. from 20.12.2011

[2*] Substituted w.e.f. 12.03.2012

[3*] Added w.e.f. from 12.03.2012

[4*] Added w.e.f. from 30.10.2019