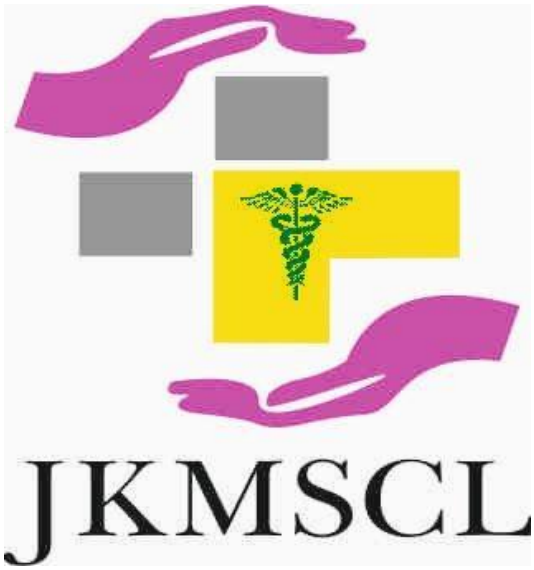

Quality Control Policy

&

Procedure

JAMMU AND KASHMIR MEDICAL SUPPLIES CORPORATION LTD.
Public Sector Undertaking of Govt of Jammu & Kashmir
Corporate Head Office:1ST Floor, Drug Store Building, Govt. Medical College, Bakshi Nagar, Jammu
Websites: www.jikmsclbusiness.com; Email: mdjkmscl1@gmail.com, gmjjkmscl@gmail.com, gmkjkmscl1@gmail.com

Quality Control Policy & Procedure

Introduction

Jammu and Kashmir Medical Supplies Corporation Limited; a fully state owned public limited company, is nodal agency for procurement, warehousing and distribution of generic drugs, medicines, surgicals, sutures, equipments / machinery and allied items with "Zero Quality Tolerance" at affordable price for inter-alia various Government Health and Medical Institutions of J&K State through e-bidding (open tender process).

In order to ensure the quality procurement and distribution of drugs, medicines, surgical, sutures, etc, Quality Control Policy and Procedures of Jammu and Kashmir Medical Supplies Corporation Limited are as under:

1. Tender Process for Empanelment of Laboratories:

1.1 GLP certified, NABL accredited Drugs Testing & Analytical Laboratories of Union of India shall be considered for empanelment through limited/ open tender system (e-bidding) under two cover system (Cover A – Technical bid and Cover B – Financial bid).
The documents to be demanded under Cover A shall include:-

i. Approval on Form 37 of Drug and Cosmetic Act, 1940 and amendments made there under issued by State Licensing Authority.

ii. Renewal on Form 38 of Drug and Cosmetic Act, 1940 and amendments made there under 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 2 years

v. Compliance to Schedule L-1 of Drugs & Cosmetics Rules, 1945.

vi. List of equipments along with their specifications installed/ operationalized in laboratories.

vii. List of technical staff along with their qualification & experience.

viii. Latest Non-Conviction certificate issued by State Licensing Authority (not before one month).

ix. Total numbers of samples tested (category wise) in last three years (Year-wise).

x. Audited Balance Sheet of last three financial years.

xi. Item-wise/ molecule-wise tests to be carried out.

xii. Item wise / molecule wise rates of testing charges (to be quoted in BOQ only).

xiii. Accreditation/ Certification.

xiv. Average turnover limit per annum of Rs. 25 Lakhs for the preceding 3 years.

xv. Government Laboratories, Research & Development Laboratories shall be exempted from the turnover criteria

xvi. Any other condition(s), specified by the Jammu and Kashmir Medical Supplies Corporation Limited from time to time.

1.2 Labs for testing and analysis of Drugs, medicines, surgical sutures, etc. shall be empanelled by JKMSCL on the basis of L1 rates and matched L1 rates per item / molecule, out of technically qualified laboratories

1.3 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. 50,000/-

1.4 The Corporation may decide to carry out inspection of the laboratories by team of experts from Drug and Food Control Organization, J&K and Jammu and Kashmir Medical Supplies Corporation Limited, which may be decided from time to time by the

Corporation to assess Good Laboratory Practices (GLP) compliance and capacity to undertake the testing work. However, the drug testing lab already empanelled with the Rajasthan Medical Services Corporation/ Tamil Nadu Medical Supplies Corporation Ltd. during the last/ current financial year shall be exempted from inspection at the discretion of the Jammu and Kashmir Medical Supplies Corporation Limited.

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

2.1 Stock of medicines received shall be entered by the warehouse in-charge in Register as well as in computer under intimation to Corporate Office/in e-Aushadhi software (when commissioned).

2.2 Stock of medicines shall be kept in QUARANTINE AREA.

2.3 Samples shall be drawn as per the quantity prescribed for testing and analysis at random by the officer / officials of respective DDW from each batch of Drug, Medicine, Surgical Sutures, etc. received at warehouse(s) as notified on day to day basis as per sampling plan framed / issued by the Corporate Office.

2.4 The samples drawn in warehouses shall be duly packed; sealed and outer packing duly signed by members of the team /officer/Incharge and shall be sent along with requisition slip to Corporate Office of the Jammu and Kashmir Medical Supplies Corporation Limited through the courier / special messenger to reach the next day at Corporate Office Jammu/ Srinagar. Information in respect of despatch shall have to be given telephonically and through mail/fax to the Corporate office.

2.5 In case, consignment of a specific batch which has already been sampled and sent for analysis is received after five days in any of the DDW of JKMSCL, random sample shall have to be drawn as given in clause 3.3 from the said consignment and to be sent for analysis as

per standard procedure. In this case the outer packing of sample &forwarding slip shall bear the remark as "Re-sampled -Same batch received after 05 days gap" so that the Corporate office can get the said sample tested from another laboratory.

2.6 In order to ensure the quality / efficacy of drugs during the storage period, the Jammu and Kashmir Medical Supplies Corporation Limited shall draw and analyse drug samples lying in the warehouses for more than 6 months to check the availability of active ingredients not below 95% through the shelf life.

2.7 In case of specific complaint or any suspicion or reporting regarding the quality of drugs, team of officers constituted by the Corporation shall have to visit the site of complaint within a minimum possible time to carry out on spot enquiry, random sampling of the items / molecules (drug, medicine, surgical suture, etc.) under question and to issue necessary directions / orders on case to case basis, which may include temporary stoppage of further distribution, withdrawal of stock from specific location or specific drug ware house or all the drug ware houses of JKMSCL.

2.8 Any designated officer of JKMSCL during routine inspection of Drug Ware house(s) may also randomly take the sample(s) of medicine(s) found suspicious or stored for a period of more than six months or found visibly altered in terms of physical parameters like change in colour, consistency, etc.

2.9 Samples taken as per clause 3.7 and 3.8 shall have to handed over to Quality Control Section at Corporate Office Jammu/Srinagar for further necessary action under intimation to General Manager (Administration), GM (QC) and Managing Director, JKMSCL.

3. Process Adopted for sample Analysis:

3.1 Samples of common batches of each item / molecule received at the corporate office from all the warehouses, shall have to be mixed and

three sample portions per batch (each portion containing minimum required quantity for testing and analysis) shall be segregated.

3.2 The particulars like Manufacturer's name, Batch no, Mfg. Date, Exp. Date, Mfg Lic. No. etc of sample portion to be sent for testing/ analysis shall be concealed either by using black indelible ink marker pen or the tablets and capsules shall be removed from the strips and blisters; and labels of those of vials, ampoules and bottles shall be removed and thereafter sample portions be properly assigned code with secret number.

3.2.1 Remaining two portions shall be kept in original packing but duly packed and similar secret code numbers shall be assigned on them and kept in the Drug Control/ sample Room at Corporate Office.

3.2.2 All relevant entries shall be made in register.

3.2.3 Portion meant for testing shall be sent to different Empanelled Laboratories for analysis as per Quality Control plan of the Jammu and Kashmir Medical Supplies Corporation Limited. Requisition slip to accompany with the sample shall bear the generic name, specification and strength of drug and secret code number only.

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

3.4 The secret code number shall be manually generated till full implementation of e-Aushadhi software and selection of laboratories for analysis shall be kept confidential and it shall be decided by the higher level officers based on the performance and backlog with the labs.

3.5 Locally samples shall be sent through messenger and outside city they shall be sent through courier with proper follow up to ensure that it reaches the labs, the next day.

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

4.1 All the tests mentioned in Indian Pharmacopeia (IP), British Pharmacopeia (BP), United States Pharmacopeia (USP), Drugs & Cosmetics Act., 1940 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).

4.2 "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.

4.3 Every test report must have remarks "Standard Quality" or "Not of Standard Quality".

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

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

4.6 Reports shall have to be attached with Spectra/Chromatography data sheets.

4.7 Report should be e-mailed to Corporate Office, Jammu and Kashmir Medical Supplies Corporation Limited at jkmsclj@gmail.com; gmjjkmlscl@gmail.com, mdjkmscl1@gmail.com apart from sending it by fax/courier/speed post.

5. Line for Analysing and Furnishing Report:

5.1 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 24 hrs of receipt of test report, information in appropriate format shall be uploaded to the Jammu and Kashmir Medical Supplies Corporation Limited website.

5.2 All test reports should be submitted by the labs in triplicate. In case of failure of sample, the result should be communicated to the Jammu and Kashmir Medical Supplies Corporation Limited 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.

5.3 If due to any reason like breakdown of the instrument, non-availability of the reference samples etc., the analytical laboratory is unable to undertake analysis of sample, the same should be reported within 24 hours by fax/e-mail and the sample should be returned to the Jammu and Kashmir Medical Supplies Corporation Limited.

6. Acceptance Criteria and Retrieval Mechanism:

6.1 If such sample passes quality test in all respects as of "Standard Quality", the results shall be up-dated to the warehouses through email / e-aushdhii updates with instructions to issue such items to various Government hospitals/Institutions.

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

6.3 If the drug fails in ASSAY or any other parameters, immediately letters shall be issued to the warehouses to freeze the stock and ask them to remove from the main stock and kept separately labelled with a mark "NOSQ- TO BE REPLACED" and the said stock / batch shall have to be replaced by the supplier (manufacturer, direct importer, dealer).

6.3.1 If another Empanelled Laboratories/Government Analyst confirms the failure of drug supplied by supplier, stocks shall have to be lifted by the supplier within thirty days and intimation in this regard shall be sent to Drugs Controller, J&K.

6.3.2 After 30 days of the letter for return of stocks, if stocks are not taken by Supplier and are lying in the warehouses, penalty of 2% per week shall be levied on the value of stocks lying in the warehouse upto 90 days, after which, the said stock / batch of drug / medicine etc. shall be destroyed by the Jammu and Kashmir Medical Supplies Corporation Limited at the cost of supplier.

6.4 In case of any failure reported by the Government Analyst on the samples drawn by the Drug Control Officer from the Storage points / Drug Distribution Centre (hospitals), immediately a letter shall be communicated to the Warehouse in-charges to stop the issuance of the product and also request them to retrieve the drug supplied to the hospitals, with copy to supplier for information.

6.5 The Warehouse in-charge shall, in turn, issue letters to each and every Institution where the batch has been supplied for retrieval of the drugs and request hospitals to recall 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.

6.6 Total value of product / item declared as of "Not of Standard Quality" shall be deducted from the amount due, on account of supplies made or performance security or any other amount due with the Corporation and action as admissible under penalty clause of tender document / quality manual / SPP of the corporation or as deemed fit by MD, JKMSCL depending upon the nature of failure, shall be initiated against the supplier.

6.7 In case of report as 'Not of Standard Quality" for any drug / sample drawn from the hospital (s) / end user institute by the officers from Drug and Food Control Organization, J&K, the said organisation (D&FCO, J&K) shall be requested to draw additional samples of the same drug (different Batch Nos.) (or) other drugs supplied by the same company from different locations in the State, to verify the quality of the drugs.

6.8 Jammu and Kashmir Medical Supplies Corporation Limited shall also take steps to verify the cumulative ASSAY value of each drug so as to ensure the availability of minimum 95% of actual ingredients throughout the shelf life. In case of consistent lower ASSAY value, the GM(QC) / Assistant Director (QC) may call for Batch Manual Record (BMR) of specific batch nos., purchase invoice and test protocols of Actual Pharmacoepial Ingredients (API) used in manufacture of batch.

7. Vaccines & Serums:

7.1 The supply of vaccines and serums are allowed to be distributed to the hospitals as per the clearance test report of CRI, Kasauli. In addition to this, samples of Vaccines shall 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.

7.2 In case of any adverse reactions reported in the Hospitals during administration of any Vaccines, Serums or any Injectables, the

Warehouse in-charges shall be requested to act immediately and to inform the same to the Corporate Office over phone as well as in writing; freeze the drug and retrieve all the stocks from the Hospitals. 8A). Testing of (1) Surgicals & Sutures (2) Biological products & Blood Grouping Reagents.

Surgical, Sutures, Biological products & Blood grouping reagents categories of drugs shall be tested on random basis from each batch supplied. Sterile products will be tested for sterility and Bacterial Endo toxin test (wherever prescribed) from empanelled labs. These items shall be released for distribution on the basis of quality test report received from JKMSCL empanelled Labs as of "standard quality".

8. Payments:

8.1 No advance payment towards any analysis shall be made to the empanelled tenderer.

8.2 No payment shall be made for the incomplete analysis or incomplete report.

8.3 Payments towards the analysis of Drugs, Surgicals and Sutures shall be made along with Tax at the prevailing rate as applicable at the time of payment.

9. Penalties:

9.1 For any delay more than stipulated in para a 6.1 (I) & 6.1 (II) as the case may be, liquidated damages shall be charged as per following schedule:-

S.No.	Delay	Penalty to be levied
1.	Delay upto one fourth period of the prescribed delivery period	2.5%
2.	Delay exceeding one fourth but not exceeding half of the prescribed delivery period	5%
3.	Delay exceeding half but not exceeding three fourth of the prescribed delivery period	10%

9.2 The liquidated damages for incomplete testing of samples shall not be less than 10% and exceed depending on the nature and critical aspect of leftover test. However this condition shall not apply when corporation consents or asked to carry out certain specific test only.

10. Blacklisting Procedures on Quality Failure:

10.1 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 shall be cancelled and the Earnest Money deposited by the tenderer shall stand forfeited to the Jammu and Kashmir Medical Supplies Corporation Limited. Such tenderer(s) shall also be liable for all damages sustained by the Jammu and Kashmir Medical Supplies Corporation Limited by reasons of breach of tender conditions. Such damages shall be assessed by the Managing Director, Jammu and Kashmir Medical Supplies Corporation Limited whose decision shall be final.

10.2 Non-performance of any tenderer or violations of empanelment conditions shall disqualify a laboratory to participate in the tender for a period as decided by Jammu and Kashmir Medical Supplies Corporation Limited.

10.3 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.

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

10.5 Based on the recommendations of In-charge Quality Control cell, Managing Director, Jammu and Kashmir Medical Supplies Corporation Limited shall 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 shall not be entitled for any compensation whatsoever in respect of such termination.

11. Resolution of Disputes

11.1 In all matters pertaining to the tender, decision of the Managing Director, Jammu and Kashmir Medical Supplies Corporation Limited shall be final and binding.

11.2 In case the parties are aggrieved with the decision of the Managing Director, he / she / they may refer the dispute for arbitration for which the arbitrator shall be appointed with the mutual consent of both the parties. The arbitration proceedings shall be governed by J&K Arbitration and Conciliation Act, 1996.

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 cities of Jammu and Srinagar.