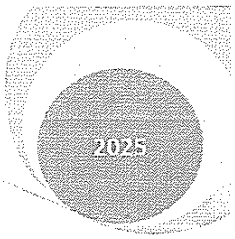


Vital Aspects of Quality Control Division

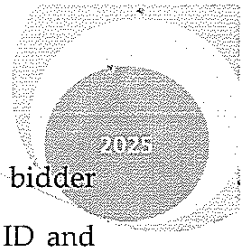
The Quality Control Department of KMSCL recommends and ensures stringent quality parameters for the drugs and items procured and distributed to the Government healthcare institutions throughout the state. The division consists of QC approval section and QC assurance section.

QC Approval Section: The section mainly dealt with the sanctioning of QC approval through online DDMS (Drugs Distribution & Management system) software for the batches intended for supply by the supplier. The QC approval will be given only after scrutinizing the respective In-house/NABL/CDL/NIB certificates submitted by the supplier in accordance with the QC Manual and the official monographs like IP, BP, USP etc.

QC Assurance section: The section manages continuous quality assessment of procured products throughout its shelf life. In case of any complaint received from the institutions, public, Doctors, Medias etc, the available stock will be frozen through online DDMS software, payment will be with held and samples of the batch drawn from the point of complaint will be tested for quality.

The stringent Quality Control Procedures followed for the Drugs/Items procured and supplied through Kerala Medical Services Corporation are as follows:

1. To ensure the quality of drugs supplied by the firm, inspection of the manufacturing facility is mandatory in the Tender. Officers from Drugs Control Department, Govt.of Kerala / Govt. Pharmacy College are included in the inspection team. The firm will be eligible for supplying drugs to the Corporation in accordance with the report from the Inspection team.
2. In order to avoid look-alike labels of different tablet formulations, the bidder shall obtain an approval from the QC Division of the Corporation for the primary



packing labels of tablets within 15 days of receipt of the letter of intent. The bidder has to send the details of the packing and labeling to the respective mail ID and after verifying the labels, the reply mail is given to the concerned bidders regarding the approval/correction.

3. Those eligible Manufacturers have to submit in-house test reports and NABL (National Accreditation Board for Testing and Calibration Laboratories)/NIB/CDL reports of the products intended to supply to corporation before dispatching the stock. QC approval team of Quality Control Division (QCD) verify the test reports and confirm that the test reports are complete and covering all the parameters as prescribed in the official monograph (IP/BP/USP/IS/ISO), Quality Manual or other standards for the item. The status of each Batch will be updated as "Approved" or "Rejected" or "Clarification sought" in the Drugs Distribution & Management System (DDMS) on-line software and can be accessed by the manufacturer by using their login Id and password. Thus the supplier shall obtain QC approval for each batch before dispatching the products to respective warehouses scheduled in POs.
4. To ensure the quality of items supplied, Corporation empanels NABL accredited Laboratories. They are selected only after rigorous Expression Of Interest (EOI) process and after receiving the inspection report of an expert committee comprising of Government Analyst and Drugs Inspectors from Drugs Control Department. Even after this, test reports of these laboratories will be continuously and rigorously monitored by the Quality Control Division to ensure the quality.
5. The Corporation adopts the following measures to ensure the quality of drugs procured and distributed:
    i. Random Sampling
    ii. Complaint Sampling
    iii. Statutory Sampling
    iv. Consistency Study

i. **Random sampling:** Not less than 30% of samples will be selected for random sampling from every item supplied by the firm (from 2021 onwards). Those selected samples will be forwarded to Quality Control Division and starts the process of Quality checking at the empanelled laboratories of the Corporation after masking the name of drugs, name of the manufacture etc. A unique sample code/label generated from the software of the Corporation will be affixed to these masked samples and forwarded to Empanelled/Drug Testing Laboratory for quality control analysis in order to avoid biasing of the NABL laboratory. Those items fail in the analysis at Empanelled laboratories, the subject batch of item was sent for quality analysis at Govt. District Drugs Testing Laboratory (DTL) under Drugs Control Department. If any batches were declared as Not of Standard Quality (NSQ) by the Govt. District Drugs Testing Laboratory (DTL), Thiruvananthapuram, the matter will be intimated to the Drugs Controller and those batches were subjected to Statutory Analysis. If the batches were declared as of Not of Standard Quality (NSQ), directions will be issued to all warehouses of the Corporation to stop the distribution of the NSQ item and recall the same from user institutions and move to quarantine area with proper labeling. If the batches were declared as Standard Quality, the same will be released for further use.

ii. **Complaint Sampling:** If any complaint is raised for any batches supplied by the Corporation, those batches will be freezed and the subject batches were sent for quality analysis. If the batches were declared as Not of Standard Quality (NSQ) by the Govt. District Drugs Testing Laboratory (DTL), Thiruvananthapuram, the matter will be intimated to the Drugs Controller and those batches were subjected to Statutory Analysis. If the batches were declared as of Not of Standard Quality, directions will be issued to all warehouses of the Corporation to stop the distribution of the Not of Standard Quality (NSQ) item and recall the same from user institutions and move to quarantine area with proper labelling. If the batches

were declared as Standard Quality then the same will released for further use. For those items which have to be kept at cold storage condition (2°-8°C) and narcotics items will be sent for Quality Control analysis at National Institute of Biologicals or Central Drugs Laboratory or any other authorized laboratories through Drugs Control Department in case of complaints.

iii. **Statutory Sampling:** Drugs Inspector (DI) under Drugs Controller, Kerala will also take batches supplied by the Corporation for statutory analysis as per Drugs & Cosmetics Act.

iv. **Consistency Study:** When 3 or more batches of a particular product declared as not of standard quality by the Govt. Analyst of Drugs Control Laboratory under Drugs and Cosmetics Act, 1940; the product will be under provision of blacklisting. The procedures for consistency study as a part of continuous evaluation will be initiated for product came under blacklisting purview. If two or more items supplied by the supplier are blacklisted based on the procedures described under blacklisting of products, then the firm itself will be blacklisted as per the procedure mentioned in the Tender of the Corporation.

6. To avoid skipping of drugs from QC analysis, first batch of drugs in every purchase order is selected for quality analysis. Further to ensure the quality of drugs, when a product comes under blacklisting purview, the samples of remaining available batches will be subjected for continuous quality evaluation.
7. If Product(s)/Bidder/Supplier is blacklisted /debarred by another state/Central Government agency, action will be taken against the supplier as per the tender condition of the Corporation.
8. Selected items (Blood Diagnostics Kits / Reagents and Medical Devices) from tender III-VIII were undergone sample evaluation. Sample evaluation is conducted by experts from the Institutions under DME & DI IS. The expert committee "approved protocol" is used for the sample evaluation for each item. After coding the item,

each item is given to four different centres of Govt. hospitals which include GH, DH and MCH. Thus one product has four testing centres. On the "expert committee" meeting EVALUATION PROTOCOL is evaluated and final decision will be taken to accept or reject the products.

9. To ensure the quality of drugs procured and supplied by the Corporation, a TOLL FREE NUMBER (1800-425-0945) was implemented for reporting all complaints including Adverse Drug Reactions. The TOLL FREE NUMBER is displayed in front of the pharmacy of all Govt. hospitals. In addition to that COMPLAINT REGISTRATION FORM is also provided to the institutions so that patients can register complaints on their own.

The details regarding the quality of medicines procured and distributed by the Corporation during last three tender years are given below.

Details of NSQ products

Sl No	Tender Year	Total no.of samples received	Total no.of samples analysed	% of testing	Total no.of samples declared as NSQ	Blacklisted Product
1	2021-22	7,934	4,367	55.04%	107	1
2	2022-23	8,858	2,426	27.39%	37	0
3	2023-24	11,739	2,688	22.29 %	17	0

Details of NSQ percentage

Sl No	Tender Year	Total No: of Suppliers	Total No: of batches received	Total No: of Samples actually analysed	Total No: of samples decleared as NSQ	% NSQ
1	2021-2022	134	7,934	4,367	107	1.349
2	2022-2023	132	8,858	2,426	37	0.418
3	2023-2024	118	11,739	2,688	17	0.145

5/2/2025

QC-M