INTRODUCTION:

With the mandate of "Zero tole[illegible] Quality Control systematically addresses and applies quality management to the development and implementation of our processes. Quality document fully and correctly describes the Quality Management System in practice. Controlled copies of this Manual are issued to members of the management of JKMSCL. Any chapter or sub chapter may be amended independent of the rest of the manual. The entire manual may also be re-issued, at the discretion of the Management.

The quality policy and objectives are documented statements as part of Quality Manual. The issue of quality manual is restricted. MD, JKMSCL approves the manual / revision of any part of the manual. GM (Quality Control) ensures that currently valid documents as applicable are available at points of use. Records are maintained at nominated locations and are easily retrievable.

Quality Procedure:

- Stock of medicines received at Distt. Drug house will be entered by the in-charge warehouse in the Register as well as in computer.
- All the Stock of medicines will be kept in QUARANTINE AREA.
- Head office will be immediately informed about receipt of stock.
- 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.
- The Warehouse in-charges and other members (who may be notified on day to day basis as per sampling plan which will be communicated by head office), shall draw samples from the random number boxes indicated by the computer system from middle and bottom layer of the boxes and send 02 samples to Quality Control section at the Head Office within 2 days from the date of receipt of supplies. The item wise sampling quantity to be drawn will be provided from head office to all DDW's.
- 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 JKMSCL through the courier/special messenger to reach the next day at head office of corporation. Information in respect of dispatch shall also have to be given telephonically and through e-mail / fax to the head office.

On account of quality failure/procedure of drugs & medicines:

1. On receipt of adverse quality test report from empanelled lab or Govt. Lab of a quarantined stock, instructions will be issued immediately to the concerned District Drug Warehouses not to release such stock and entries be made by QC Cell at headquarter for batch rejection i.e. not to be released for distribution to institutions.
2. Warehouse Incharge will take appropriate measures immediately to segregate such stock and label all cartons as "NOSQ Drugs-Not for release" and shift it from quarantine area to Non-Release / Rejected Drugs Area till its lifting by the supplier if required.
3. Immediately on receipt of NOSQ report, the second sample should be sent to another empanelled lab / Govt. Lab by the QC Cell.
4. On receipt of test report from empanelled lab / Govt. Lab, show cause notice will be issued immediately to the concerned supplier calling for explanation within 3 days The supplier shall be informed immediately about the test results and instructions be issued to lift the entire stock at supplier's expenses of such batch no. drug which is declared as "NOSQ" by the empanelled lab / Govt. Lab. However, in case of **serious quality failure i.e. if drug is declared spurious, adulterated or grossly substandard,** the State Drug Controller shall be contacted for drawing statutory sample of such batch as per Act.
5. In case of drug declared as **Not of Standard Quality** on subsequent sampling after the batch was released, district drug warehouse in charge will take immediate steps to RETRIEVE the unused stock of such drugs from all such institutions and DDW's ensuring effective recall.
6. On confirmation of the test result by the second laboratory, the case will be processed for further appropriate action based on merits of the case and impose penalty including blacklisting of the particular product/company or firm as deemed fit besides forfeiture of security deposit.
7. In case when the second report is contradictory to the first report, the statutory sample will be sent to Govt. Lab, whose report will be final and if the sample has been tested by the Govt. Lab at any stage, its report will be conclusive & final and binding upon suppliers.

8. Purchase Orders, if any, already issued before taking any blacklisting action or replacement orders given in past will not be affected in view of action taken as per above guidelines but all strict quality checks shall be observed for each supply of products.
9. If two batches of a particular item supplied during contract period by the supplier are declared as Not of Standard Quality by an empanelled lab **in test for assay** and such failures are further confirmed by another empanelled lab/Govt. Lab, then the particular drug shall be blacklisted for a period of not Less than 2 years.
10. If three batches of a particular item supplied during the contract by the supplier are declared as Not of Standard Quality by an empanelled lab or Govt. Lab **in test for assay and / or in any other parameter(s)** during its entire shelf life, the particular item of the drug shall be blacklisted for a period of not Less than 5 years.
11. In case 50% of products supplied or three products, whichever is less, of a company/supplier are blacklisted for supply made during the Bid duration the Supplier / Company shall be liable for blacklisting for a period of not Less than 2 years.
12. If a single batch of any product is declared as Spurious or Adulterated or misbranded during entire shelf life by an empanelled lab or Govt. Lab and if such failure is further confirmed by another empanelled lab/Govt. Lab, the Supplier / Company shall be blacklisted for a period of not less than 5 years.
13. If a single batch of any product is declared as Grossly Sub-Standard during entire shelf life by an empanelled lab or Govt. Lab and if such failure is further confirmed by another empanelled lab/Govt. Lab, product shall be blacklisted for a period of not less than 2 years.
14. If any statutory sample of JKMSCL supply drug is drawn by Drugs Control Officer on suo-moto basis or on complaint and if it fails in quality parameters, the report shall be conclusive and binding on the suppliers. However if failure is of such nature wherein Drugs Controller of State grants prosecution sanction under Drugs & Cosmetics Act, 1940, then even failure of such one batch shall be considered adequate for blacklisting the product for not less than 2 years and in case of involvement of three different products the **Supplier / Company** as a whole shall be liable for blacklisting for a period of not Less than 3 years.

ORGANOGRAM: