QUALITY MANUAL

(Reference Guideline: ICH Q10: Pharmaceutical Quality System & ISO 9001)

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1. Introduction

A quality manual or equivalent documentation approach should be established and should contain the description of the pharmaceutical quality system.

Quality manual shall be given document number as S/QM-00. Where S-SOTAC, QM-quality manual and 00 is superseded number.

Quality manual should be review once in three year or whenever required.

The factory is situated in Sanand GIDC -II, which is approx. 25 km away from Ahmedabad City and 45 km away from Ahmedabad International Airport. The area is neat and clean without pollution and thus is an ideal place for pharmaceutical plant.

The facility has total plot area about 2791.50 SQ. MT. SOTAC PHARMACEUTICALS LTD. has different departments like Warehouse Quality Assurance, Quality Control, Engineering Maintenance and Production/Packaging Operations. The most responsible person for this unit is Mr. Sharad Patel a Managing Director of SOTAC PHARMACEUTICALS LTD.

ADDRESS: PF-21, Sanand G.I.D.C – II, Charal Industrial Estate,
Sanand GIDC-II,
Sanand-382110, Ahmedabad, Gujarat

Company History

During 2016, **SOTAC PHARMACEUTICALS LTD**. was incorporated at Ahmedabad for commissioned solid /oral manufacturing facility in Sanand GIDC-II, located at Ahmedabad, India. So far the exhibit/pilot/commercial batches manufactured at the site are being submitted to relevant regulatory authorities for approval.

Authorized pharmaceutical manufacturing activities

The site is constructed for manufacturing of solid/oral drug products in various forms including Tablet/Capsule/Suspension/Gel/Syrup/Topical Ointment.

2. Quality policy

We are in the business of Manufacturing and Marketing of Finished Drug Formulations (e.g. tablet, capsule, oral liquid and topical ointment) which demand very high Quality Standards.

We are fully committed to build quality of our Products, Processes, Systems and Employees through-

- Practicing Total Quality Management [TQM] Principles with special emphasis on GMP and Cost Effectiveness.
- Adherence to high standards of Health, Safety and Environmental Norms.

- Continuous training and development of our employees for continual improvement of the pharmaceutical quality system.

3. Management Responsibility

3.1 Management commitment

For Successful implementation, maintaining and improvement of this internal Quality Management system, the senior management is committed for following duties.

a) Establish Quality policy and objective.
b) Appoint and support a quality manager.
c) Approve the Quality manual & Site master file.
d) Ensure the availability of resources.

Senior management has the ultimate responsibility to ensure an effective pharmaceutical quality system is in place to achieve the quality objectives, and that roles, responsibilities, and authorities are defined, communicated and implemented throughout the company. #

Quality is an important element in the success of organization. A quality policy document and top management's commitment to the quality of the product, play an important role in the quality system.

Management Functions whose work affects Quality (With reference to this manual) are listed below:

1. Managing Director
2. Quality Assurance In-charge
3. Production In-charge
4. Quality Control In-charge
5. Warehouse In-charge
6. Packing In-charge

The aforementioned persons in the execution of their duties shall include responsibility for:

The quality of work carried out by their respective personnel allocation and delegation of specific quality related activities to nominated, authorized and suitably trained personnel within their respective department.

Ensuring that their personnel are familiar with and have access to the company's Quality policy, Quality Manual and necessary procedures.

Responsible to ensure processes are in place to assure the control of outsourced activities and quality of purchased materials. #

The Quality Assurance Head / Designee irrespective of any other responsibilities has the authority and responsibility to ensure that the system and procedures referred to this manual are implemented and maintained, initiate action to prevent the occurrence of the product.

Ensuring timely and effective communication and escalation to raise quality issues to the appropriate levels of management. #

Non-conformity:

- ✓ Identify and record any product quality problems.
- ✓ Initiate, recommend or provide solutions through designed channel.
- ✓ Verify the implementation of solutions.
- ✓ Control further processing, delivery [or installation] of non-confirming product until the deficiency or unsatisfactory conditions have been corrected.

In the execution of these duties the Quality Assurance Head / Designee is responsible for the verification of procedures, practices and systems including the organization of audit relating to the quality system. In this respect the Quality Assurance Manager has the additional responsibility as quality assurance coordinator (Management representative)

When auditing the process and quality control department, the QA coordinator shall have the responsibility and authority for this audit, and reporting to the Director.

3.2 Customer focus

One of the high priority objectives of SOTAC PHARMACEUTICALS LTD. is customer satisfaction. Any expression of dissatisfaction related to quality, therapeutic action and packing of drug product is considered a complaint. Complaint is investigated as well as complaint sample is tested for applicable parameters as per defined SOP. Investigation outcome is communicated to customer.

All employees are committed to work in compliance with SOPs and cGMP norms which ensure continuous delivery of products meeting its predetermined quality attributes.

3.3 Planning

3.3.1 Quality objectives

Main quality objective of SOTAC PHARMACEUTICALS LTD. is to deliver the quality products continuously which meet its predetermined quality attributes. Quality management system, process, procedure is developed and training is imparted to employees to ensure that these objectives should met. The effectiveness of quality management system is analysed and reviewed at specified frequency.

The main quality and business objectives of SOTAC PHARMACEUTICALS are:

(a) Continuous delivery of quality products which meet its predetermined quality attributes
(b) Implementation of quality manual & continuous improvement

3.3.2 Quality Management system planning

Planning is carried out to ensure implementation of Quality management systems. Validation master plan, calibration schedule, self-inspection plan, product quality review plan which covers the plan of activities for specific time period as defined in SOP. Quality management review is performed twice in year in order to review implementation & effectiveness of quality system.

3.3.3 Responsibility, authority and communication

The responsibilities and authorities of all employees including senior management are defined in ' Job responsibility' as per SOP, which is allocated by reporting authority and consent by employee. All employees are committed to work in compliance with SOPs and cGMP norms.

4. Management Review:

Continuous implementation and effectiveness of quality management system is reviewed by senior management with means of Quality management review program and self-inspection.

Management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the cGMP requirements and the stated Quality Policy & objectives. Records of such reviews shall be maintained.

The Quality System shall be reviewed annually. If any changes require, quality manual should be revised through the change control procedure.

The quality system review meeting will be chaired by the Managing Director and attended by at least any three of the following personnel,

- ✓ Quality Assurance In- charge and/or designee
- ✓ Production In - charge and/or designee
- ✓ Engineering In - charge and/or designee
- ✓ Quality Control In- charge and/or designee #

The agenda and review input shall include,

- ✓ Minutes of the previous meeting and follow-up action from previous meeting.
- ✓ Review of the site quality system
- ✓ Process performance and service conformity.
- ✓ Status of Corrective and Preventive Actions
- ✓ Review of the internal quality audits and their corrective action requests
- ✓ Review of quality defects and customer complaints.
- ✓ Changes affecting the management system.
- ✓ Improvement and Recommendation

Review Outputs shall concluded
The outputs from this review include actions and decisions in relation to

- ✓ Improvements in the effectiveness of the QMS.
- ✓ Required resources *I* training requirements.
- ✓ Required audits.
- ✓ Customer service and delivery improvements.

5. <u>Personnel:</u>

Specifying a set of quality requirements or issuing detailed procedures through manuals and procedures will not achieve the desired results unless adequate resources are provided for various jobs including verification.

The HR Department along with senior management shall be responsible for identifying and selecting appropriate resources, inducting them with the respective departments, imparting training, looking after their welfare and providing administrative support.

Senior management and HR are responsible to recruit the employee considering education and experience, which ensure the implementation, improvement and effectiveness of QMS

Competence, awareness and training

Job responsibility is defined for each employee which lies with personal records and trainings. Personnel are gone through induction programme like cGMP, personal hygiene, and company introduction before commencing job. Training need is identified and training should imparted to employee. Training programme is handled by manual system by coordinator and each training is evaluated.

Records of employee history, job description, appraisal shall be maintained in HR department.

Work Environment

Appropriate work environment, open culture and avenues are established for employees to express their opinion through Progress Reports. Its include appropriate office space, IT infrastructure, utilities and facilities. HR Department shall look after these areas and monitors its effectiveness

Health & Safety issues are considered and appropriate practices implemented to ensure safe and working conditions. Employees undergo health check-up before joining organization as well as every year after joining organization. Any person suffering from disease shall notify to supervisor & not enter in classified area if required.

Infrastructure

All functional areas have adequate infrastructure to comply regulatory requirements and quality systems. This includes buildings, workspace, equipment, vehicles, communications, ·information systems and supporting services.

The HR Department shall also be responsible for general administration including housekeeping, safety, health, firefighting etc.

6. Quality System: (Quality Management System)

6.1 General Information:

Documentation consists of several tiers of documents, each successive tier becoming more detailed. At the apex is quality manual which describes all the elements of a quality system that the organization required to meet the quality requirements.

"Quality management system is established in order to ensure that the company continuously monitors, measures, maintains and improves the quality of products"

It helps in developing effective monitoring and control systems for specified process performance that in turn establishes the capability of processes. It is useful for identifying and prioritizing areas for continual improvement in terms of quality attributes, process technology and other technical aspects.

These objectives ultimately contribute to the betterment of end product quality and better process understanding. The design, organization, and documentation of the quality system are detailed enough in order to facilitate common understanding. The effectiveness of the QMS is regularly audited, reviewed and improved.
The Quality Management System is designed based on the requirements I guidance by CSFDA, EC, PIC/S, Health Canada, WHO and other regulatory agencies. Where processes are outsourced, appropriate control over these processes is implemented. This includes vendor evaluation and selection, material verification and contract agreement

6.2 Documentation Requirement:

6.2.1 General

In SOTAC PHARMACEUTICALS, Documents are classified in four levels for better control. Level I document defines approach (i.e. Quality policy, Site master file, Quality manual, Validation master plan, calibration manual). Level II defines who, what and when things happen (i.e. SOP, Master MFR/MPR/BMR/BPR, and Validation protocol). Level III defines how thing happen (i.e. specification, method of analysis. change control form & complaint). Level IV defines evidence of occurrence (i.e. standard format, log book, exhibit records).

6.2.2 Quality Manual

Document specifying the quality management system of an organization. It is supported by documents e.g. Standard operating procedure (SOP), Deviation, Change Control, OOS, CAPA, Quality Risk Management, Complaint, Product Recall etc.

SOP: All the critical processes are governed through relevant standard operating procedures, which are prepared by the respective department and approved by Quality Assurance Head *I* designee after review by relevant department heads.

Deviation: Any departure from pre-established process or parameter is handled by Deviation system. Deviation is investigated, evaluated and approved by QA head as defined in SOP.

Change control: Any change *I* introduction of the system *I* document *I* equipment *I* area are controlled by Change Control, after intimation to the respective department and approval by Quality Assurance head.

Out Of Specification: Any result generated by quality control, analytical research & development or by a contract laboratory, that falls outside the laboratory test results limits specified in current applicable specification, is considered out of specification.

Corrective and preventive actions: The corrective and preventive actions taken for prevention of occurrence and recurrence of non-conformances are handled through procedure for Corrective Action and Preventive Action (CAPA).

Quality Risk Management (QRM): The Quality risk management at the site has been adopted from ICH's guideline for Quality Risk Management (ICH Q9) in order to minimize risk. Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product. Quality risk management is governed by a standard operating procedure.

Complaint: Any expression of dissatisfaction related to quality, therapeutic action and packing of drug product is considered a complaint. Complaint is investigated as well as complaint sample is tested for applicable parameters as per defined SOP. Investigation outcome is communicated to customer.

Product Recall: Product recall is firm's removal of correction of marketed product that a regulatory agency considered to be in violation of the laws. Recall does not include market withdrawal or a stock recovery. Product recall) is handled as per defined SOP.

6.2.3 Document and Data Control

The documentation done in the unit is manual. Electronic documentation is also available in case of laboratory equipment and some equipment in manufacturing, engineering.

QA department is responsible for ensuring correct preparation, revision, approval, distribution, control and archival of documents.

Key documents are developed, prepared as per standard formats.

Examples:

(1) Standard operating procedures.
(2) Specifications used to release Raw materials, intermediates and finish products and their testing methods.
(3) Qualification and validation protocols and reports.

Each document is approved by QA head which becomes master copy of document. Master copy of each document is further used for issuance of control copy, reference copy. Documents are issued by QA person. Documents are revised through change control system. Review revisions are issued only after retrieval of old revision.

All live documents, supersede documents and cancelled documents are stored and preserved by QA.

Establish and maintain documented procedures (including approval, issue and changes of documents and data) to control all necessary documents related to Manufacturing and Quality Assurance.

(NOTE: Documents and data can be in the form of any type of media, such as hard copy or electronic media.)

All procedures and necessary documents relating to and in connection with the quality system of the location shall be uniquely identified by means of document name, code, amendment number and date (where applicable)

In case of controlled procedures, it is responsibility of the departmental heads to implement it effectively and maintained.

It is responsibility of QA to ensure that documentation relating to quality system is distributed in accordance with the document control procedures.

Customer imposed standards shall also be included under the requirements of controls.

Procedures detailing authority, responsibility, actions and records are documented, maintained and listed within the SOPs & records.

6.2.4 Repacking and redressing shall be carried out under following cases.

- ✓ Goods available in BSR since long and still not expired.
- ✓ Government supply cancelled and goods still live.
- ✓ Export supply manufactured but not dispatched due to any commercial issue.
- ✓ Accidental return goods.
- ✓ Redressing of goods on revision of expiry period.

The quality system is designed to ensure that the customer receives a product to agreed specifications, delivered on time, whilst maintaining all aspects of product and package quality.

7. Customer Review:
Customer-related processes

Determination of customer requirements, parameters shall be established before commencing commercial batches manufacturing based on various analysis & study during product devolvement in order to meet customer health requirements. Ranges for parameters are determined and listed for each product. These parameters are monitored, and tested during batch manufacturing. Each batch is verified by qualified employee to ensure that parameters meet the specified criteria prior to batch release.

Customer's any expression of dissatisfaction related to quality, efficacy and packing of drug product is considered a complaint. Complaint shall be investigated as well as complaint sample shall be tested for applicable parameters. Investigation outcome shall be communicated to customer within appropriate time line in accordance with criticality of complaint.

Review of Customer requirements.

Periodic review shall be carried out by senior management for complaints, which includes the trend analysis based on repeated nature, causes and criticality as well as review by senior management during quality review steering meet. Appropriate actions shall be recommended if required in order to meet customer requirements and satisfaction.

Customer communication

Necessary information about products is provided to customer via website and literature inserted with product. Critical information related to product i.e. its content, adverse effect, storage, precautionary instruction are covered in literature that is provided along with product. SOP is defined to maintain and record any oral and mail communication made by customer regarding dissatisfaction from product.

Design and development

Design and development activity includes formulation development study and technology transfer to commercial facility in which cGMP and quality aspects are kept into account during design and development of product.

8. Purchasing Control:

8.1 Evaluation and selection of supplier.

The suppliers and manufacturers of raw & primary packing materials used for batch manufacturing are qualified prior to the commercial production of the batches as per the procedure for vendor qualification. The supplier or manufacturer is qualified for each raw material that is procured. The raw material & primary packing material supplier are considered qualified for supplying a raw & primary packing material, provided the following parameters are met

- Questionnaire based evaluation
- Site audit to ensure manufacturer's compliance with cGMP as applicable.
- When tested by SOTAC PHARMACEUTICALS (including any testing contracted to a contract laboratory), three different lots from the same manufacturer, meet specification with results comparable to the raw/primary packing material manufacturer's results.
- Quality agreement with vendor.

8.2 Purchasing information

Purchase orders are used to purchase any key instrument or equipment material. Numbering of purchase order and information are governed through ERP system. Purchase order contains information related to amount, description of item, approvals etc.

8.3 Verification of purchased product

Purchased products are verified against purchase order. Raw materials are tested for applicable tests and ensured compliance to specification before usage. Equipment is verified by conducting design qualification, installation qualification, operational and performance qualification.

9. Product Identification and traceability:

All the materials are received at site, after scrutiny, through warehouse. Stores receive materials carries out general inspection and register the receipt. After approval from QC the material are issued to the manufacturing. In case of rejection, the materials are returned to the suppliers or destroyed at the site in well-defined area.

Material movement i.e. Incoming materials and outgoing materials are controlled by stores. Planning of raw materials, packaging materials, inventory is controlled by Production Planning and Inventory Control dept.

Approved raw materials are issued to the manufacturing department and final products are received by stores dept. Dispatch of approved final products is looked after by Stores dept.

Raw materials, Packaging materials shall be identified by name and unique code no. and final products by name and Batch No. system to ensure a secondary specific identification for products, raw materials and packing materials.

All products during manufacturing will be identifiable by the product name and batch number.

Upon completion products will be clearly labeled to include the product name and batch no.

The numerical batch number as displayed on all packed products will defines, the machine on which product manufactured, product code, Year of manufacturing, and serial no. of the batch.

Throughout production, testing, storage, and dispatch all accompanying documentation, product will display clearly the product name and batch number.

10. Process control:

All processes shall have adequate written procedures for manufacturing and control as mentioned in Batch Manufacturing Record (BMR)*.

Production planning & Inventory Control department gives monthly schedule for manufacturing to the Production manager.

The Quality Assurance Department is responsible for preparation, revision and distribution of all documents for manufacturing.

The Quality Assurance Department issues scanned Batch Manufacturing Record (BMR)* saved in computer system for manufacturing a batch. The BMR* consists of a Formulation Order and a Packaging Order. The Formulation Order is as per the Master Formula issued by the QA department and which has been fed into the computer. Access to update this Master Formula on the computer is restricted only to Quality Assurance Manager.
The batch is then manufactured as per the Manufacturing Instructions given in the BMR. Every operation requires a 'doer' and 'checker' signatures. In-process checks are carried out at predetermined time intervals by both Production and In-process Quality Assurance Inspectors and recorded in the BMR. Samples of intermediates and finished goods are checked by Quality Control personnel and review the complete Batch Production Record to ensure compliance with cGMPs during the manufacturing. The Quality Assurance Manager then releases the batch for distribution.

Reconciliation of raw materials, bulk product and packing materials forms part of Batch Production Record.

A Change Control Procedure controls any change in manufacturing procedures, change in vendors, equipment, process, formulation etc. and this has to be approved by the Quality Assurance Manager.

11. Inspection and testing:

The Quality Control Department is part of the Quality Assurance Department shall be responsible for Inspection and Testing. The major activities of the Quality Control Department are:

i) Testing of raw and packaging materials
ii) Testing of in-process samples
iii) Testing of finished products

Raw material, packaging material, In-process and finished products will be tested by quality control personnel to ensure compliance with the specification.

Raw material and packaging material shall be strictly controlled upon receipt to ensure that all activities relating to inspection and testing are carried out prior to use in production department.

Analysis procedures as required will be in accordance with Pharmacopoeias And/or in-house tests as mentioned in respective STPs/MOA.

In case final product release the Batch Production Control Record shall be reviewed by the Quality Assurance department. QAM (Quality assurance management) checks for the completeness of the document and for the compliance with cGMP at various steps. The QA Manager Releases the batch for distribution by signing the Batch Production Record.

All analytical data shall be recorded and retained with the QA department for the specified period.

Environment monitoring is performed in the area where environment affects product directly or indirectly. Monitoring of viable count, non-viable count, temperature, relative humidity, differential pressure is carried out as per defined procedure.

12. Control on inspection, measuring and test equipment:

Key equipment involves in critical manufacturing activity shall be validated and calibrated before use. Equipments are qualified for design, installation, operation & performance before usage for manufacturing activity as per defined procedure. Preventive maintenance is performed for equipment at specified frequency in SOP. Any breakdown in equipment is recorded, evaluated and rectified. Any modification in equipment's addressed through change control system, which is evaluated and approved before commencing.

Instruments are calibrated against criteria specified in respective SOP. Procedure and frequency is defined for calibration of instrument. Instrument is not used if not comply with predefined calibration criteria. Schedule is maintained for calibration of instrument. Daily verification of instrument is performed to verify instrument

operation if applicable as per defines SOP. All equipment in the laboratory is calibrated as per the pre-determined frequency. Records of such calibration are maintained.

Computerized systems are used in the issue of batch Production Records and Inventory Control of raw and packaging materials shall also be validated as per SOP.

13. Control of non-conforming products:

Non-conforming product is segregated and labelled appropriately. Non-conforming product is withheld from release in market. Investigation is carried out and corrective and preventive actions are recommended. Non-conforming product is destroyed after approval of senior management

14. Quality Risk Management: #

Quality risk management (QRM) is integral to an effective pharmaceutical quality system. It provides a proactive approach to identifying, scientifically evaluating and controlling potential risks to quality. It facilitates continual improvement of process performance and product quality throughout the product lifecycle.

QRM applies at various stages of pharmaceutical process to identify, assess, control, and communication of risk as per defined SOP.

15. Corrective and preventive actions:

The corrective actions for the material failing to conform to specification shall be proceed as per instructions and authorization by Quality Assurance Manager.

Corrective and preventive actions in case of product / batch, does not conform to specifications, shall be taken by the Quality Assurance Manager in consultation with Managing Director.

Any market complaint received by QAM shall be investigated and handled as per SOP.

In case of product recall, Quality Assurance Manager informs to Head of Marketing through E-mail, telephone or fax informing him to stop the sale of product. This is followed by a written communication by QAM , by fax/courier, to all depot locations within India and to Regional Directors and Country Managers in case the product is distributed in overseas market as per SOP.

The stocks are stored in Quarantined Area at the manufacturing location till all investigations are completed by the Quality Assurance Manager.

The Regulatory Authorities are informed about the batch recall and its reconciliation.

All resultant procedural modifications and changes to the quality system arising from the assessment of defects will be recorded and documentation amended as per SOP.

All plant and process modifications will be handled by QAM and Managing Director .

Co-ordination of all such modifications, corrective & preventive actions, and their effect on the quality system is the responsibility of QAM and Managing Director.

Procedures detailing authority, responsibility, actions and related records are documented and maintained within the respective SOPs and records.

16. Handling, storage, packaging, preservation and delivery:

Proper handling requires careful planning, effective control and documented procedures from the time the materials enter the factory until the finished product reaches the customer. Organization shall develop its own procedures and instructions to comply the requirement of quality system.

Warehouse department shall playing important role in the requirements for handling, storage, packing, delivery and safety of the products and materials.

Handling during transfer, storage, dispatch and delivery shall be in accordance with the relevant procedure. In-process material shall be handled as specified within manufacturing procedures.

All products and materials will be labeled indicating name, batch no., product code.

Procedures detailing authority, responsibility, actions and related records are documented and maintained within the respective SOPs.

Analysis of data

Product quality review is performed yearly. Product Quality Review provide a systematic approach, to evaluate all commercial products on an annual basis to determine if there are any developing trends and/or need for taking corrective and preventive actions.

Trending of complaints, change control, deviations are carried out periodically based on nature, categorization, causes etc. Trending summary includes tabular data as well as graphical representation. Trend evaluation becomes source for prioritize and initiation of corrective and preventive actions for improvements.

Improvement

Quality management system i.e. deviation, change control, OOS, complaint, recall, internal audit, trend analysis becomes source to initiate corrective and preventive actions in order to bring improvements in quality system. Corrective actions are taken to eliminate the causes of existing nonconformity in order to prevent recurrence and Preventive actions are taken to eliminate the all possible causes of potential non-conformity in order to prevent occurrence. Corrective and preventive actions are derived by technical committee which contains subject matter experts. CAPA procedure includes identification of cause, determination of CAPA, implementation of CAPA, verification of implementation and CAPA effectiveness evaluation.

17. Control of quality records:

Quality records provide the objective evidence that the requisite product quality has been attained, and that the various elements of the quality system have been effectively implemented.

The respective departmental manager/ head or his representative shall ensure all records are maintained to avoid deterioration, damage or loss.

Retention of quality records will be in accordance with the following table,

RECORDS	LOCATION	RETENTION
Analytical	Laboratory	1 year after expiry
Calibration	Engineering	6 year
Quality	QA	Permanent
BMR*	QA	1 year after expiry
Audit reports Quality review minutes	QA	Permanent
Personnel	HR	Permanent
Inter departmental Correspondence	All dept.	6 year
Departmental Quality related	All dept.	6 year

18. Internal quality audits: (Self Inspection):

A quality audits is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements, and whether these arrangements are implemented effectively and are suited to achieving the desired objectives.

Self Inspection on all systems, procedure and operations shall be conducted regularly in order to monitor compliance with and the effectiveness of cGMP and Quality Assurance principles in the various operations and to allow for improvement and corrective measures where required.

19. Training:

The specification, control and assurance of product quality can be carried out only by competent personnel. Therefore requires documented procedures for identifying training needs and for training all personnel performing activities affecting quality, specifies qualifications, training and motivation as the key factors in achieving quality.

Training is a continues process and the management and departmental head shall, by request or observation identify and initiate the ongoing training requirements of employees, to maintain and develop the quality and efficiency of operations.

All new employees will provide induction training to emphasis company rules and to initiate familiarization with the company and workplace operations.

Staff/employees appraisal will be conducted annually by their relevant manager to identify and mutually agree the development and training requirements of the employee within the organization.

The in-house training program consists of:

Induction program

cGMP requirements

Safety
Hygiene
Training on use of equipment (on-the job training)

Process operators shall be trained in accordance with the need as assessed by the departmental head. Managers/Departmental heads are also send for training program conducted by various professional bodies / outside experts. Records of such training shall be maintained.

20. Statistical techniques:

Quality Assurance Manager and Production Manager shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

Establish and maintain documented procedures to implement, control and application of statistical techniques identified.

Commonly used statistical techniques are sampling inspection. This determines the quality of a lot or batch of products on the basis of a small sample of the product. This can be used for receipt inspection, in-process inspection and final inspection.

The aim is to eliminate the causes of quality problems and thus to prevent product nonconformity.