Nasense Labs Private Limited

SITE MASTER FILE

Address
Plot Numbers 24 & 25
SV Cooperative Industrial Estate, Jeedimetla
Quthbullapur (M), Hyderabad – 500 055
Andhra Pradesh, India

Contact Details
Security: +91 40 64 64 35 70
Stores: +91 40 64 64 35 71
Corporate Office: +91 40 64 64 35 72
Fax: +91 40 23 71 35 72
<table>
<thead>
<tr>
<th>Activity</th>
<th>Employee Details</th>
<th>Role in the Company</th>
<th>Date</th>
<th>Signature</th>
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<tbody>
<tr>
<td>Preparation</td>
<td>Anvesh Lanka</td>
<td>Business Development Manager</td>
<td>March 14, 2013</td>
<td></td>
</tr>
<tr>
<td>Review</td>
<td>Arjun Gottumukkala</td>
<td>Plant Manager</td>
<td>March 15, 2013</td>
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<tr>
<td></td>
<td>K Anusha</td>
<td>Assistant Manager – QA</td>
<td>March 15, 2013</td>
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<tr>
<td>Approval</td>
<td>Goutam Gottumukkala</td>
<td>Managing Director</td>
<td>March 18, 2013</td>
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<tr>
<td></td>
<td>GRK Raju</td>
<td>Chairman</td>
<td></td>
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Chapter 1 - General Information

1.1 Name and Exact Address of the Site

Nasense Labs Private Limited

Manufacturing Facility (Site)
Plot Numbers 24 & 25
SV Cooperative Industrial Estate
Jeedimetla, Quthubullapur (M)
Hyderabad - 500 055
Andhra Pradesh, India

**GPS Coordinates:** +17° 31' 22.46", +78° 27' 8.02"

**Telephone (Security):** +91 40 64 64 35 70
**Telephone (Stores):** +91 40 64 64 35 71

Corporate Office
8-3-222/B/14, Plot No. D-70, Sri Sivalaxmi Nilayam
Behind Vellanki Foods
Madhuranagar
Hyderabad - 500 038
Andhra Pradesh, India

**GPS Coordinates:** +17° 26' 25.08", +78° 26' 12.14"

**Telephone:** +91 40 64 64 35 72 (73/74)
**Fax:** +91 40 23 71 35 72
1.2 Brief Introduction to the Company

M/s. Nasense Labs Private Limited is a recently established progressive organization, engaged in integrated-production of specialty molecules and pharmaceutical products. It was founded in 2006 by Mr. GRK Raju, a pioneering expert in the Indian Chemical Industry, renowned for having developed a stable high-conversion process for the manufacture of Sodium-based products. The company is now being headed by Mr. Goutam Gottumukkala, a graduate scholar in pharmaceutical biotechnology from the University of Pennsylvania, Philadelphia.

Our company has a multipurpose state-of-the-art manufacturing facility in Jeedimetla – Hyderabad, and also a high-tech R&D Lab for process design and evaluation of upcoming products. Our core products are a set of high-precision tools for organic syntheses, used in a variety of chemical processes across multiple industry sectors.

Although we are recent entrant in the pharmaceutical industry, our engineering and process design competences enable us to produce high quality products in a maximally-efficient and reduced-effluent-load system. In the near future, we plan to incorporate biocatalysts into our product range.

1.3 Manufacturing Activity (List of Products)

Some of our important products include Sodium Hydride (60% Dispersion in Oil), Sodium Amide, Dextromethorphan Hydrobromide, and Risperidone and Paliperidone Intermediates. Over the last few months, we have been working on the Iodine line of catalytic compounds. We have developed systems to manufacture Sodium Iodide, Potassium Iodide, Sodium Metaperiodate, TMSI, Methyl Iodide and Hydroiodic Acid (45-55%), and are parallelly developing a number of other derivatives (Please refer to www.nasense.com for the full list).
1.4 **Type of Products Manufactured at the Site**

Fine Chemicals and Pharmaceutical Ingredients (Including Intermediates)

1.5 **Other Activities**

- We perform contract manufacturing activities for companies like Aurobindo Pharma and Posh Chemicals. We also undertake R&D projects for local pharmaceutical companies.
- Right now, we are working on a recycling process involving the extraction of Iodine from the Iodine-Mother-Liquor (Effluent) generated by a number of companies.

1.6 **Brief Description of the Site**

This facility has been established as per ISO (9001:2008) standards for the manufacture of specialty molecules. It is managed by experienced technical staff under the guidance of the company’s top management (in conjunction with expert advisors). Please refer to Annexure 1 for our ISO Certificate, Annexure 2 for our Plant Layout and Annexure 3 for our Facility Equipment List. Some of the important parameters have been detailed below.

- **Total Land Area**: 1.92 Acres
- **Total Constructed Area**: 7094 m²
- **Total Reactor Volume**: > 110 KL
- **Number of Reactors**: 34
  - **Number of SS Reactors (Range)**: 26 (0.1 to 8 KL)
  - **Number of GL Reactors (Range)**: 2 (4 KL)
1.7 Employee Details

The site is headed by the Plant Manager. The following details the number of employees working in full-time (permanent) or equivalent positions in different departments. Please refer to Annexure 4 for our Organizational Chart.

<table>
<thead>
<tr>
<th>Department</th>
<th>Number</th>
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<tr>
<td>Production</td>
<td>60</td>
</tr>
<tr>
<td>Quality Control</td>
<td>9</td>
</tr>
<tr>
<td>Research and Development</td>
<td>10</td>
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<tr>
<td>Quality Assurance</td>
<td>4</td>
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<tr>
<td>Other</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>115</strong></td>
</tr>
</tbody>
</table>

1.8 External Assistance in Company Activities

A majority of the company's activities are conducted in-house (either in the QC Lab or in the R&D Lab). However, we sometimes enlist the assistance of reputed and competent commercial laboratories for additional analyses. We ensure that none of the relevant legal provisions are infringed in any case. Some of their details have been given below.

**Sigma Analytical Testing House Private Limited**
47-1B, Sri Sai Colony, Chintal, Hyderabad – 500 054, Andhra Pradesh, India

**Startech Labs Private Limited**
2nd Floor, SMR Chambers, 1-58/7, National Highway 9, Madinaguda, Hyderabad – 500 050
Andhra Pradesh, India
1.9 Brief Description of the Company’s Quality Management System

We have integrated our quality systems in line with the requirements of ISO (9001:2008) standards, and are now working on a process-oriented approach to quality systems in order to satisfy current and emerging customer needs consistently.

Achievement of quality is the prime responsibility of all the functional heads. They are tasked with ensuring that the systems function as per the procedures listed out in the quality management system manual. They are also required to account for deviations of any form.

Our main objective is to develop a production-centric, GMP-compliant, ‘zero-defect’ system that allows for continuous improvement in the long run.

Responsibilities of the Quality Assurance Department

- Ensuring that all procedures are as per the Standard Operating Procedures
- Assessment of Personnel Competence Levels
- Evaluation of Procedures and Validations
- Preparing, issuing and updating the Quality Assurance Policy
- Maintaining and controlling all documentation related to technology transfer (if any)
- Audit operations to assess the adequacy of existing QA systems
- Monitoring of Key Quality Indicators

Responsibilities of the Quality Assurance Manager

- Evaluation and approval of all validation protocols
- Assigning raw materials and packing materials
- Approval of final specifications
- Specification of sampling procedures
• Evaluation and approval of all final SOPs
• Evaluation and Approval of all final QC-prepared Standard Analytical Procedures
• Review and approval of all BPRs prior to the release of goods for distribution, in order to ensure compliance to GMPs (if applicable) during the manufacture of any product
• Audit and approval of Vendors and Contract Manufacturers
• Evaluation and analysis of Complaints and Batch Recalls
• Routine Stability Testing of Finished Products
• Checking for updates in Pharmacopoeias

The Quality Assurance Manager is assisted by the Quality Control department in a number of activities. Sometimes, even the Research and Development department acts as a support centre for Quality Assurance.

**Responsibilities of the Quality Control Manager**
• Conducting specification tests on all raw and packing materials, as well as finished products
• Preparation of Specifications
• Preparation of Standard Analytical Procedures
• Providing support to the activities of the Quality Assurance Department

**Self Inspection**
• Self-Inspection and Quality Audits are carried out once in every 4 Months, to detect shortcomings in the implementation of the Good Manufacturing Practices mentioned in the Quality Manual. Recommendations are made to ensure necessary corrective actions.
• Members of the Inspection Team
  ▪ Quality Assurance Manager
  ▪ Production Manager
  ▪ Departmental Head (of the department being inspected)
  ▪ Internal Auditor
Vendor Development

- All starting materials are procured from approved vendors. In case of a new supplier, audit of the site is undertaken by the Quality Assurance Manager.
- The technical and financial strengths of the supplier are judged using a standard checklist.
- Existing suppliers are assessed on a continuous basis using Routine Audits.
- Similar practice is followed for suppliers of Packing Material.
Chapter 2 - Personnel

2.1 Organizational Chart

Our Organizational Chart has been appended as Annexure 4.

2.2 Details of Key Personnel

- Our Founder and Chairman, Mr. GRK Raju, is a Chemical Engineer from Osmania University. He is a Post Graduate Scholar in Safety Engineering and Management, with an experience of over 40 years in the Chemical and Bulk Drug industry.

- Our Advisor for Engineering, Mr. Kuppuswamy, is a Chemical Engineer from IIT-Chennai and has worked for over 30 years in the field of Chemical Engineering Design.

- Our Advisor for Research and Process Development, Mr. YP Rao, is a renowned specialist in Process Design and Optimization. Over the past 35 years, he has been a key contributor to the process engineering developments undertaken by companies like Lupin, Cipla and Dr. Reddy’s.

- Our Advisor for Quality Assurance, Mr. Nagadhar Varma, is a technopreneur with previous experience in Pharmaceutical Quality Assurance. At the moment, he is assisting us in the implementation of a GMP-compliant Quality and Material Management Software called GMP Pro.

- Our Managing Director, Mr. Goutam Gottumukkala, is a Graduate Scholar in Pharmaceutical Biotechnology from the University of Pennsylvania, Philadelphia.
2.3 Basic and In-house Training (including Record Maintenance)

The training program includes induction, basic training and continuous in-house training for all new trainees (probationers also, if required). Training is done as per existing and updated internally developed procedures.

- Training needs are defined by the departmental heads in consultation with the Managing Director.
- Assessment Points are identified and described similarly.
- The annual training plan is scheduled by the HR Department.
- The Training program Circular is distributed as and where required.
- Training Progress is recorded (including Attendance). The employee training record is later used to judge the employee's effectiveness.
- Once the training is complete, the employee is assessed as planned. This is noted in the Employee Evaluation Form, based on which recommendations are passed.
- Once this is complete, the HR department tracks the training implementation status for the year, and uses this information to provide a summary of the training needs for the next year.
- The Quality Assurance and HR departments play a support role in personnel assessment and retraining.

2.4 Health Requirements for Production Personnel

Adequate measures have been taken to ensure that the employees remain in good health, and work in a safe and risk-free environment. Information on possible infections (and other afflictions arising out of work activities) is freely available at the unit. For preventive purposes, some of the staff members have been trained to identify harmful symptoms relating to any part of the manufacturing activity.

The HR department is responsible for initial, routine and regular medical checkups for employees. This information is to be documented as warranted.
2.5 Personal Hygiene Requirements (Including Clothing)

- Personnel should practice the basic sanitation and health habits prescribed by the company.
- Housekeeping Records should be maintained and updated regularly.
- Personnel should wear clean clothing suitable for the manufacturing activity in which they are involved. Additional protective apparel, such as head, face, hand and arm coverings should be worn if necessary, to protect contamination and hazards.
- Personnel should avoid smoking, while at the facility.
- Food should be consumed only in the designated areas.
- The company does not encourage jewellery, makeup, tobacco-chewing or beards for personnel employed in production areas. Please keep it to a minimum.

- The company has provided the following to ensure that the personnel work in a clean setup. All personnel are encouraged to make the best use of these resources.
  - Clean Drinking Water
  - First Aid
  - Fire Extinguishers
  - Washrooms and Toilets
  - Lighting Arrangements (as required)
  - Proper Ventilation (wherever feasible)
Chapter 3 - Premises and Equipment

Part A  Premises

3.1  Plant Layout

Our Plant Layout has been appended as Annexure 2.

3.2  Details of Construction and Finishing

- The factory complex is securely provided with a compound wall on all sides. The entire structure has been constructed using RCC Material.
- The production floor is of hard concrete with adequate drainages and ventilation.
- The QC, Instrumentation, Stores and R&D departments have been housed in areas with a smooth concrete floor.
- Wherever required, AC Sheet Roofing has been used.
- All the areas have flameproof electric wiring systems to ensure optimal electrical connectivity to each and every machine.
- Some areas have been provided with flameproof lights and other luminaries to allow for good lighting conditions.
- All aspects of safety and emergency have been considered, and sufficient preventive measures have been implemented.
- The factory is designed to provide easy access to exits during times of emergency.
3.3 Ventilation Systems

Appropriate arrangements have been made to ensure optimal ventilation in the factory. Windows ceiling fans have been provided in all areas except those for manufacturing, filling, packing and sealing.

For areas involving critical operations, centralized/singular air conditioning units have been provided. A total of 6 Air Handling Units have been provided, with support for temperature and humidity controls.

The corridors are also environmentally controlled, and are maintained at positive pressure as compared to the individual rooms to prevent mixing (if any) of air/powder in the rooms and corridors. The air handling system has been pressure-balanced to prevent cross contamination.

3.4 Special Areas for Handling Toxic/Hazardous/Sensitizing Materials

Special areas have been provided in the Warehouse, for handling toxic, hazardous, corrosive or sensitizing materials. In such areas, no other materials are stored.

3.5 Water and Treatment Systems

- The facility has provisions for both Municipal as well as Bore Water.
- The Raw Water is stored in a holding tank first, and then transferred to a Storage Tank.
- Here the water is tested for pH, Conductivity, Hardness, Sulphate Content, Chloride Content, Magnesium Content etc using Hydrochloric Acid and Caustic Soda Flakes.
- If the quality of the water meets the required specifications, it is passed on to manufacturing operations. If the quality is low, then it is transferred to the cooling tower.
• In emergency situations, for process (manufacturing) requirements, water is procured directly from reputed suppliers.

Please refer to Section 8.2 for details of our Treatment Systems.

### 3.6 Preventive Maintenance Program (Including Record Keeping)

The entire facility is maintained in a clean and tidy condition, with weekly review of all areas. All details are recorded in a Log Book, and Checklists are provided for verification during the next Maintenance Review. We are now planning to incorporate a Preventive Maintenance Policy with allowance for Weekly, Monthly, Quarterly and Annual Reviews with specific objectives.

The Preventive Maintenance Team consists of the following members. This team conducts routine checks every Saturday. They are responsible for checking each and every part of the factory, to rectify areas that may require additional maintenance.

- Quality Assurance Manager (or Executive)
- Managers from the ‘Engineering and Maintenance’ Department
- Managers from the Respective Areas being checked

### Part B Equipment

### 3.7 Equipment used in the Company’s Activities

A majority of the equipment (Generic as well as customized) has been procured from reputed manufacturers in the field. The designs are as per internationally accepted norms and make use of the best materials available (GMP Models).
Apart from the usual chemical industry setup, we have installed two Nitrogen Gas Generation Plants, One Hydrogen Station, One Chilling Plant, and One High Performance Boiler House.

Please refer to Annexure 3 for our Facility Equipment List.

3.8 Preventive Maintenance Program (Including Record Keeping)

Equipment maintenance is performed on the basis of SOPs available with the QA department. The ‘Engineering & Maintenance’ and ‘Production’ personnel are responsible to ensure this. Details of such maintenance are recorded in the Equipment Log sheet and Equipment Status Card. An annual preventive maintenance schedule is drawn up by the E&M and QA managers for all equipment.

The SOPs detail the following checkpoints.

- Periodicity of Preventive Maintenance
- Method of Preventive Maintenance
- Checks/Replacements to be performed

3.9 Qualification and Calibration (Including the Recording System)

Prior to actual usage, it is compulsory to qualify, validate and calibrate all the equipment installed at the facility. Validation involves the following steps.

- Installation Qualification
- Operational Qualification
- Performance/Process Qualification (This will be implemented soon)
A team consisting of representatives from the Production, QA and Engineering departments performs all three validation steps on the basis of the SOPs provided by the QA department.

Equipment Calibration is performed once in every month in the following manner.

- **Calibration**: QC Department
- **Supervision**: Validation Team
- **Support**: The personnel/department directly involved in operating the Equipment

All these activities are recorded in log books, and checklists are maintained to ensure verification and review (if required).

**Part C   Common for both Premises and Equipment**

**3.10 Written Specifications and Procedures for Cleaning Processes**

Written Procedures are available for cleaning of both the manufacturing areas and the equipment. The SOPs for this are available with both the Production as well as the Quality (both QA and QC) departments.

**Cleaning Procedures for Manufacturing/Support Areas**

All the areas in the facility are cleaned daily as per the respective SOPs, which define the disinfecting agent and concentrate to be used.

**Cleaning Procedures for Equipment**

- The equipment used in manufacturing operations is cleaned at the end of the shift as per the respective SOPs.
During product change-over the machine parts are dismantled, washed with water, and air-dried.

After a series of three such washes, the production executives inspect the equipment and note its status on the Equipment Clean Tag. Further washes are performed, if required.

At the end of each batch, filters are also vacuum-cleaned.

Prior to start up of any equipment, the in Quality executive certifies the equipment is clean and may be used. This certification becomes the part of the BPR.
Chapter 4 - Documentation

4.1 Preparation, Revision and Distribution of Manufacturing Documentation

- The QA department is responsible for the preparation, issue and revision of the QA policy. It is also responsible for the preparation, revision and distribution of all Manufacturing Documents.

- All Master Documents are stored by the QA department. Every master document has a review period, and it is reviewed mandatorily on or before that date. Circulation of these documents is restricted. This is controlled by the issuing QA department. On approval, these are prominently marked as ‘Master Copy’. Copies of the same are marked as ‘Control Copy’, and distributed to all concerned departments.

- If any changes are to be made to these documents, the entire document is rewritten, duly prepared, reviewed, and finally approved by three independent but relevant personnel. All preceding copies of the document are destroyed, except one copy. This is kept for reference purposes and is prominently marked as ‘Obsolete Copy’. Documents are stored for up to one year after the Expiry Date of the Material.

- It is also the responsibility of the QA Department to maintain and control documentation related to the following.
  - Approval, Issue and Withdrawal of all SOPs
  - Specifications of Raw, In-Process, Intermediate, Final-product and Packing Material
  - Sampling Methodology for all the above
  - Approval of Material against these Specifications
  - Approval, Storage, Retrieval, Review and Destruction of Batch Process Records
  - Validation and Calibration Protocols for Equipment, Processes and Systems
  - Change Control Procedures (Manufacturing, Vendor, Equipment etc)
  - Documentation from the Research and Development department
Chapter 5 – Production

5.1 Description of Production Operations

The QA Department issues a Batch Production Record (BPR) for the manufacture of a batch. It consists of a Master Formula, Manufacturing Instructions and a Packaging Order. The Master Formula is issued by a committee comprising of the following employees. The committee retains full control over its revision.

- Chairman
- Managing Director
- Production Manager
- R&D Advisor
- R&D Manager

The Batch is then manufactured as per the manufacturing instructions given in the BPR. Every Operation requires ‘Performed by’, ‘Checked by’ and ‘Authorized by’ Signatures. In-process checks are carried out at predetermined time intervals by both the Production and QC departments, and relevant details are noted in the BPR.

The QC department checks samples of Intermediates and Finished Goods. If the batch meets the required specifications, the Quality Assurance Manager reviews the BPR to ensure compliance with GMPs, and releases the batch for distribution.

5.2 Handling, Sampling, Quarantine, Release, Rejection and Storage of Raw Materials

Please refer to section 7.1
5.3 General Policy for Process Validation

- Validation is carried out by a team consisting of Managers from the Production and QA departments.
- Our standard policy, for any manufacturing activity is to validate all the processes before the commencing production.
- Any and all changes in a validated process will have to be revalidated before switching to it.
- A process is considered to be validated when three consecutive batches give results that fall within the specified limits.
6.1 Details of the QC Department (System and Activities)

The Quality Control Department is part of the Quality Department. It is headed by a Quality Control Manager. The department is primarily concerned with sampling, testing, documentation and release of raw, in-process, intermediate and finished materials. All activities are performed on the basis of existing Standard Operating Procedures. Please go through our Facility Equipment List, for the full list of equipments available at the QC Lab.

The following are the department’s major activities.

- Sampling
- Approval/Rejection of Raw and Packing Materials
- Testing In-process Samples
- Testing Intermediates and Finished Products
- Carrying out Stability Studies
- Testing Water and other Materials
- Provision of Support to the QA Department
- Preparation and Standardization of Volumetric Solutions

6.2 Procedure for the Release of Intermediates and Finished Goods

- As soon a batch is packed, the in-process QA personnel draw random samples of the finished products. These random samples are then tested against approved specifications provided by the QC Department.
• These Specifications are usually more stringent than Pharmacopoeia requirements. If the random samples meet the specifications (know as Product Release Specifications), the Quality Control Department approves the material, and prepares a Certificate of Analysis.

• The Batch Production Record is then reviewed by the Quality Assurance Chemist. The QA Manager checks for the completeness of the documents and for compliance with required standards, at various steps. The batch is released for Distribution after approval by the Quality Assurance Manager.

6.3 Procedure for the Release of Printed Packaging Material

• All printed packing materials, on receipt from the vendor, are stored in the warehouse with ‘under-testing’ labels.

• A Receipt Note is made for the material and sent to the QC Department.

• The QC Department assigns an Analytical Reference Number to the material, and performs sampling of the same.

• These samples are tested as per approved specifications, and are compared with approved standards using Standard Analytical Procedures.

• If the sample conforms to the specifications, then the consignment is released with an ‘Approved’ label affixed over the previous ‘under-testing’ label.

• The Consignment is then moved to the ‘Approved’ area in the warehouse.
Chapter 7 – Warehousing and Related Activities

7.1 Warehousing

The warehouse (stores) has been constructed with reinforced cement concrete columns, mild steel columns and brick walls. The entire building has been provided with adequate levels of cross-ventilation through a multitude of shutters and doors.

The materials are placed within the warehouse in separate designated areas.

Adequate care is taken to ensure the following.

- Prevention of Mix-ups between Raw Materials
- Nullification of Material Compatibility Issues
- Sufficient Space for Free Movement
- Dedicated areas for Raw, Packing, Rejected and Finished Materials

Activities

- All Raw and Packing Materials are received at the Stores. On receipt of the material, the Stores Officer (Manager) checks the supplier's documents accompanying the goods.
- The details of the incoming material are recorded in the record book and an 'Under Testing' label is pasted on the material containers. The number of labels printed is equal to the number of containers received. The goods are then stored in a separate 'Under Testing' area.
- Personnel from the QC departments draw representative samples of the batch. Sampling of raw materials, intermediates and finished products is done as per the respective SOPs governing sampling.
- The samples are then tested at the lab. If the material is approved, the QC chemist affixes an 'Approved' label on the containers and has the material moved to the 'Approved' area.
• Any raw or packing material that does not conform to the approved specifications is treated as rejected material. In case of rejection, the QC chemist affixes a 'Rejected' label on the containers and has the material moved to the 'Rejected' area. A rejection note is prepared, stating the reasons for Rejection. The stocks are moved to an area designated for rejected stock. The Purchase department informs the vendor about the rejection, along with the reasons for rejection. The rejected stocks are sent back to the vendor.

• In the warehouse, the materials are stored as per the conditions prescribed by the manufacturer. The materials are then dispensed to the production blocks either as per the Batch Process Records issued during production planning or in response to written requests from the Production department.

• During production, in-process samples are randomly tested by the QC department.

• The following documents are then checked or prepared, after which the finished goods are readied for distribution.
  - Sampling Plan
  - Packing List & Certificate of Analysis
  - Batch Process Records
  - Weighing Control

• In the case of finished goods, the rejected materials are readied for disposal, after confirmation from the production and quality departments.

• The Inventory is updated for all materials.

7.2 Distribution

• Raw and Packing Materials are issued following appropriate written requests from the production and packing departments respectively. Approved labels are compulsory. Care is taken to ensure that materials are issued only after the quantities that were previously provided are depleted.

• For finished goods, the material is readied for dispatch on the basis of the schedule and checklist provided by the marketing department.
7.3 Record Keeping for Distribution

The records of distribution contain the following details. These records provide scope for traceability from the factory to the customer.

- Batch Numbers
- Dates and Timing
- Signatures of Associated Personnel

7.4 Handling Procedures for Complaints

The main idea behind the complaint handling policy is to ensure that complaints are handled effectively, quickly, and to the total satisfaction of the customer. The responsibility of handling the complaints lies with the Marketing department.

The Quality Assurance department is responsible for coordinating investigations and implementing corrective actions.

Activities

- As soon as the concerned Marketing manager receives a complaint, the details are recorded in a ‘customer complaint form’, and this is sent to the QA department along with a note.
- The QA personnel will record this in the ‘customer complaint register’, and begin investigations into the cause of the complaint.
- The findings of the investigation and proposed corrective/preventive actions are recorded in the complaint form.
- The QA department maintains these details in a record.
- This completed complaint form is sent back to the Marketing department. These details are communicated back to the customer.
- The complaints record shall be kept at least for a year after the expiry date of the product.
7.5 **Handling Procedures for Product Recalls**

Product Recall shall be initiated for batches, which were approved for marketing at the time of their release, but are forced to be recalled due to any one of the following reasons.

- Detection of Batch Failure during Routine Stability Analyses
- Batch declared to not be of standard quality by Drug Testing Laboratories / Customer Analysis

Firstly, Reconfirmation Analyses would have to be performed on the following in events such as this. The analyses will be conducted both in-house and at an external laboratory.

- Control Samples
- Complaint Sample

**Activities**

- The QA department initiates the Product Recall action. The recall committee, consisting of the heads of QC, Production and the QA departments, will discuss and examine the issue.
- The marketing department is informed of the details of their discussion, and is to intimate the customer regarding the recall action.
- On receipt of the recalled stock, it is inspected by the Production and QA departmental heads. Decisions are taken on reprocessing or reworking actions.
- Complaints are received by the QA department, and lodged in the complaints register. These are properly investigated, and findings are recorded in an 'Investigation and Corrective Actions Report'.
- This report is sent to all departments, to enable assessment of the cause of the observed deviations. The recall committee investigates it further and finalizes the report.
- The finalized report is sent to the marketing department, to forward to the customer.
- The QA department reviews all such reports periodically to ensure that such observed deviations are not repeated.
Chapter 8 - Inspection Systems

8.1 Self Inspection System

Our Company has a defined Self-Inspection System through which all the departments are audited once in every 3 Months. This is performed by a team in conjunction with members from the department being audited.

- Members of the Inspection Team
  - Quality Assurance Manager
  - Production Manager
  - Departmental Head (of the department being inspected)
  - Internal Auditor

The audit is carried out as per prescribed SOPs and checklists. The audit program should be initiated at least one week in advance, in order to get cooperation from all concerned personnel. It should have a systems-based rather than personnel-based approach. The scope of the audit covers technical audit of production and laboratory facilities, procedures and practices. It should also cover the adequacy of and adherence to SOPs. During the audit, compliance to the observations raised in previous audits must be specifically checked.

Audits must note both deficiencies as well as the positive aspects observed during the course of the audit. The reasons for observed deficiencies, if any, must also be noted. All Deficiencies noted in the inspection are attended to by the Departmental head, and a non-conformity report is issued.

Corrective actions should be prepared by the auditor, along with the timeframe to implement them. The audit team should check for compliance at the end of this time period, and prepare and submit a final report to the Quality Assurance Department.
8.2 Activities to assess Effects on the Environment

Our company possesses all the necessary licenses and permits to carry out its manufacturing and waste disposal operations. All these operations comply with local and national regulations. Our operations are mostly based on 100% conversion processes, and as a result, very little effluent is generated. Liquid Effluent (from other processes) is treated at a common effluent treatment plant located in the area.

We still conduct random checks to measure emissions and contamination as and when required. In view of all this, we hereby certify that our operations have no negative impact on the environment.
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>BPR</td>
<td>Batch Process Record</td>
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<tr>
<td>cGMP</td>
<td>GMP-Compliant</td>
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<tr>
<td>E&amp;M</td>
<td>Engineering and Maintenance</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>GPS</td>
<td>Global Positioning System</td>
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<tr>
<td>HR</td>
<td>Human Resource</td>
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<tr>
<td>IQ</td>
<td>Installation Qualification</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<tr>
<td>OQ</td>
<td>Operational Qualification</td>
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<tr>
<td>PQ</td>
<td>Performance/Process Qualification</td>
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<tr>
<td>QA</td>
<td>Quality Assurance</td>
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<tr>
<td>QC</td>
<td>Quality Control</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>SAP</td>
<td>Standard Analytical Procedure</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<tr>
<td>TMSI</td>
<td>Trimethyl Silyl Iodide</td>
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## Revision History

<table>
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<tr>
<th>S. No.</th>
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<td>1.0</td>
<td>First Issue</td>
<td>March 18, 2013</td>
<td></td>
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