SITE MASTER FILE

I N D E X

I N D E X

A P P E N D I X

1.0 GENERAL INFORMATION

1.1. Brief Information On The Firm

Halewood Laboratories Pvt. Ltd. is a group of "IPCA" Laboratories Ltd. The company is located in Ahmedabad (Gujarat) in India , engaged in the manufacturing Loan license & Third party for more than 23 years.

On implementation of the new Industrial Policy in 1982, for Indian entrepreneurs, by the Government of India, a small pharmaceutical company M/s. Halewood Chemical Pvt. Ltd., was founded in 1982, in partnership by Mr. Kaushik S. Chaturvedi a Pharmacy graduate and young entrepreneur and Mr. Harshad Patel, . The company was initially engaged in the manufacturing and marketing of Ethical products.

In years 1991-'95, the company was doing job work for "Cadila Laboratories Ltd". Co. was started under the guidance and supervision of a young Technocrat, Mr. Pramod Jain, for the manufacturing Medicines.

In 1995, the partnership was dissolved Mr. Harshad Patel was retired as a partner of the firm & firm was engaged with "Rasna Enterprise Pvt. Ltd".

In January 1998 the firm engaged in jaobwork for "Ipca Laboratories Ltd". Also jobwork for "Rasna Enterprise" . The modern manufacturing unit was established at GIDC Vatva Ph-II Plot no.319, Near Vinzole Railway Crossing, 15 K.M. from Ahmedabad Railway Station (Ahmedabad) on Ahmedabad- Mehmedabad Road, manufacturing of Tablets, Rasna Instant Drink as per GMP - Good Manufacturing Practices.

In April-2000 this firm was converted into Halewood Laboratories Pvt. Ltd.

The progress of Halewood Laboratories Pvt. Ltd., continues at a rapid pace.

The company has a Schedule –M Certificate. The company is also getting ready for the WHO inspection to obtain the said certificate by July 2007.

1.2. Pharmaceutical Manufacturing Activities As Licensed By The Government Authorities

Pharmaceutical manufacturing activities in our country are controlled by the Director General, Drug Control of India. Licensing and controlling activity is under the control of Gandhinagar Food and Drugs Administration. As per the Drugs and Cosmetics Act and Rules thereunder, the Director General, Drug Control of Gandhinagar, approves all the new products after the submission of necessary data. The labeling of drug products is also controlled by the above Act, as well as any additional specific instructions given by the Director General, Drug Control of India at the time of New Product licensing.

Halewood Laboratories Pvt. Ltd., manufactures and distributes a wide range of pharmaceutical dosage forms under different therapeutic segments viz Anti-Tuberculosis, Anti-Malarial, Anti-Biotic, Cardiovascular, Anti-Diabetic etc. under Drug Manufacturing License Numbers G/265 & G/535 in Form Number, 25 & 28 issued by The Food & Drugs Administration, Government of Gujarat. Copy of the mentioned Manufacturing Licenses is enclosed in Appendix-I, for reference.

The company has created a separate manufacturing facility for Tablets & Rasana instant drink. Modern dedicated facilities for food products have been provided with suitable environmental controls having controlled temperature and humidity conditions.

1.3 Other Manufacturing Activities At The Site

No other manufacturing activities, except those for which the company has the Manufacturing License issued by the Government Drug Authorities, are carried out at the site.

1.4 Name and Address of the Site

HALEWOOD LABORATORIES PVT. LTD.,
319, G.I.D.C. Phase II
Vatva
AHMEDABAD
Gujarat
India.

Phone No.:
91-079-25831513
91-079-25896479

Fax:
91-079-25896494

E-mail: halewood.lab@gmail.com

Administrative Office:

HALEWOOD LABORATORIES PVT. LTD.,
319,G.I.D.C. , Phase II
Vatva
AHMEDABAD
Gujarat
India.

Phone No.:
91-079-25831513

Fax :
91-079-25896494

E-mail : halewood.lab@gmail.com

Telephone Nos. of Contact Persons

Sr. No.	Name of the Person	Designation	Phone No.
1	Mr. Kaushik Chaturvedi	Managing Director	Office : 91-079-25831513 Mobile :09824342424
2	Mr.Sanchit Chaturvedi	CEO	Office :91-079-25831513 Mobile09824314184.
3	Mr.Krutin Chaturvedi	Marketing Manager	Office 91-022-26300555 Mobile : 09820438552
4	Mr. Ram Singh Rai.	Plant Manager	Office:91-079-25831513 Mobile: 9825403103

1.5 Type Of Products Manufactured At The Site

List of Products Licensed is covered under Appendix-I

The company has a number of product permissions for Tablets in the following therapeutic range:

- Anti Malarials
- Anti Diabetics
- Cardiovascular
- Enzymes

1.6 Description of the Site

1.6.1. Halewood Laboratories Pvt. Ltd., has set up the pharmaceutical manufacturing facility at Vatva about 15 km from Ahmedabad city. The site is located in G.I.D.C. phase II Vatva 0.5 kilometer away from Vatva Railway Station. The factory has excellent infrastructure like roads, streetlights, under ground drainage system, ETP system etc. The Plant is provided with a new water purification system, excellent manufacturing and packing equipment**.**

The Production Department is located in two separate buildings – General Pharma Block for general category formulations of Pharma products and Isolated Formulation Block for Manufacturing of Rasana Products (Job work manufacturing of Pioma Food Industries (Rasana instant drink) The service departments include Raw Materials Stores, Packing Materials Stores, Finished Goods Warehouse, Quality Control Laboratory & Quality Assurance, Security Department, Account & Administration and Industrial Safety Section under Engineering Department.

1.6.2. Size of Site & Area

Plot Area	**1678.80mtrs**
Built up Area	**Ground floor-684.40mtrs** **First floor-992.40mtrs**

The area covered for each department / section is as given below:

Sr. No.	Department / Section	Area in Sq. meters.
1.	Raw Material Stores	68.62
2.	Packaging Material Stores	123.04
3.	Finished Goods Stores	57.58
4.	Tablet Manufacturing Granulations	1. 47.39 2. 46.92
5.	Tablet Manufacturing Compression	1.13.53 2. 15.58 3. 9.50 4. 8.25
6.	Tablet Packing (Bulk)	19.53
7.	Tablet Packing (Blister & Strip)	73.8
8.	Quality Control / Quality Assurance	20.28
9.	Utilities and Engineering	31.80

1.7 Employees Details:

Sr. No.	Department	Managerial / Technical	Operators / Workers	Total
1.	Production Pharma	13	75	88
2.	Production Rasna	8	55	63
3.	Quality Control / Assurance	8	03	11
4.	Stores & Distribution	05	05	10
5.	Engineering	01	03	04

6.	Account & Administration	07	02	09
			Total	**185**

1.8 External Technical Assistance

Our Quality Control facilities are self sufficient and well equipped. However, assistance from the following Government-approved public testing laboratories is sought, if required:

A. Gujarat Laboratories
Contact Person : Mr. Mukesh Bhatt
Mr. Himanshu Pandit
Lic. No. GTL / 20
F-17 Madhavpura Market
Shahibaug,
AHMEDABAD - 380004
Tele fax : 079 – 25626040, 25624821,
25625436, 25620753
E mail : gujlab@hotmail.com

B. Vaibhav Analytical Services
303, 3rd Floor, Sahjanand Shopping
Center, Near Police Commissioner Office
Shahibaug,
AHMEDABAD – 380004
Phone : 079 – 25624555, 25624330
Fax : 079 – 25624646
E mail : vaibhavlab@hotmail.com

C. Oasis Test Hous
Contact Person : Mr. Puran Saini
24 A-B Sardar Patel Ind. Estate
Narol – AHMEDAB 380004
Phone : 079 – 25712618, 25714701
E mail : oasis@vsnl.com
Web site : www.eoasislims.com

1.9 Quality Management System

1.9.1. Quality Policy

The Company has a clear, written down Quality Policy which projects the company's vision and the management's commitment to Quality, the compliance to standards going beyond customer satisfaction to customer delight and achieving the Quality objective through its infrastructure and work practices. The Quality Policy of the company is stated as follows:

Halewood Laboratories P. Limited is in the Job work Pharma business and "Pledged To Ethics" for manufacturing of quality drug products that consistently meet the comply standards by adhering to current Good Manufacturing Practices (cGMP) in its state-of-the-art plants, to alleviate the suffering of mankind and delight the customers through its unique and cost effective formulations.

1.9.2. Responsibility of Quality Assurance Function

- The authorization of written procedures and other documents, including amendments.
- Training on good laboratory practices (GLP) and current good manufacturing practices (cGMP) is carried out initially and at regular frequency as scheduled.
- The monitoring of compliance to GMP requirements.
- The monitoring and control of the manufacturing environment.
- Personnel hygiene.
- Calibration of analytical apparatus, instruments and equipment.
- Validation of analytical methods.
- Qualification of Process equipment.
- Process Validation.
- The approval and monitoring of vendors of starting materials.
- The monitoring of storage conditions for materials and products as designated.
- To approve or reject starting materials, packaging materials, and intermediate, bulk, and finished products.
- To approve sampling instructions, specifications, test methods, and other quality control procedures.
- To check the maintenance of the department, premises and equipment.
- To ensure that all necessary testing is carried out.
- To evaluate batch records.
- The inspection, investigation, and sampling, in order to monitor factors that may affect product quality.

- The retention of records as per statutory guidelines.
- To approve and monitor analysis carried out under contract.

1.9.3 Elements of The QA System

The objective expressed in the policy statement is achieved by a carefully designed quality system which incorporates the following elements:

(A) Organisational Structure.
(B) Responsibilities
(C) Quality Management Procedures.

(A) Organisational Structure

The Quality Division is headed by the Chief Executive – Quality Assurance, who is a highly qualified and experienced industrial pharmacist. He works independently and reports directly to the Managing Director of the Organisation.

The Quality Division consists of Quality Control and Quality Assurance functions, which are manned by sufficient number of qualified and experienced Analysts: Chemists, Microbiologists and Pharmacists etc.

(B) Responsibilities

Responsibilities of the Quality Control Unit as part of the Quality Assurance Function (as covered under Point No. 1.9.2.) in the Quality Management System, includes the following activities:

1. Chemical Analysis.
2. Instrumental Analysis.
3. Microbiological Analysis.
4. Packaging Material Testing
5. Retention of Control Samples
6. Preservation of Batch History Records.
7. Real Time Stability Testing
8. Certificate of Analysis

(C) Quality Management Procedures And Documentation

The quality management system has the following procedures and documents:

- Procedure for product development meeting GMP & GLP requirements.
- Clearly defined production and control procedures in the form of:
  - Master Production & Control Records. (MPCR)
  - Batch Production & Control Records. (BPCR)
  - Material specifications and Test Methods
  - Product Specifications and Test Methods

- Standard Operating Procedures.
- Training Records
- Relevant Departmental Documents.

- All raw materials, packaging materials, in-process materials and finished products are analyzed by validated test methods, against pre-defined specifications and released for distribution only after approval.
- The entire manufacturing process is carried out under expert technical supervision and a well developed in-process quality control system is in force to ensure that the processes are in a state of control.
- All the raw materials, packaging materials, intermediates and finished products are stored as per GMP guidelines provided by QC, regarding storage conditions like temperature and humidity, as applicable.
- Quality audits are carried out at regular frequency and corrective action taken for any non-conformance.
- Responsibilities of key persons are clearly defined in their job descriptions.
- All manufacturing processes are clearly defined in the batch production and control records, which are regularly reviewed for compliance.
- All critical manufacturing process are validated initially and subsequently, if any changes are undertaken at any stage of the manufacturing process.
- All activities are clearly defined in the respective department SOPs in the form of work instructions.
- All manufacturing and quality management personnel are regularly trained, as per calendar, to update their knowledge and skill.
- All manufacturing and QC records are reviewed regularly and kept updated.
- Q A has an effective product recall system.
- Retained samples are kept for each batch produced as per statutory requirements.

1.9.4. Audit Programmes

Technical audits by external authorities are carried out as per company's requirement from time to time.
A Self Audit System is designed for internal inspection, and carried out as per SOP, seeking compliance to the audit points within a fixed time frame. Such Audit Reports along with their compliance status and actions taken are recorded and updated after each audit.

1.9.5. The Self Audit Report includes a detailed questionnaire, which covers the practically all aspects of the pharma operations. The observations are discussed with the concerned personnel to take corrective actions wherever needed**.**

1.9.6. WHO GMP Guidelines serve as the benchmark for assessment of suppliers of Raw and packing materials.

1.9.7. A vendor certification system for RM and PM Suppliers / Manufacturers exists in the Company and is mainly carried out through questionnaires followed by actual visit to the supplier / manufacturer's site of operation**.**

1.9.8. Release of Finished Products for Distribution and Sale follows the defined procedure as per SOP. The system is designed to take care of Batch reconciliation from manufacturing to packaging, Batch Transfer to Bonded Stores, complete batch testing and issue of Certificate of Analysis by Quality Control Department, Batch Card Review, approval and final authorization by Quality Assurance Department of the release for distribution and sale.

***

2.0 PERSONNEL

2.1 Oranisation Chart Appendix – II

2.2 Qualifications, Experience And Responsibilities of Key Personnel.

2.2.1.

Name	:	**Mr. Kaushik Chaturvedi**
Education	:	**B. Pharm**
Designation	:	Managing Director
Experience		More than 30 years of experience in pharmaceutical industry in the field of Production & Quality control, & administration Development Domestic and International documentation from Indian and multinational organizations.
Job Responsibility	:	Total responsibility as Managing Director of Unit Development, Motivation of Staff, and management activates at Halewood Lab. for Pharma & Rasna Plant.

2.2.2.

Name	:	**Mr. Sanchit Chaturvedi**
Education	:	Master in Family Business Management
Designation	:	Chief Executive Officer
Experience	:	More than 4 years in Regulatory Affairs in the pharmaceutical industry, Domestic and International documentation for Indian and multinational organisations.
Job Responsibility		Total responsibilities for the production, Warehousing and other factory management activities at Halewood Lab. Pharma & Rasna Plant. Communication with the outside parties and Marketing for the company.

2.2.3.	Name	:	**Mr. Ramsingh R.Rai**
	Education	:	M.Sc. Organic(Drugs)
	Designation	:	Plant Manager
	Experience	:	More than 14 years of experience of Production and project, in pharmaceutical industry.
	Job Responsibility	:	To upgrade the systems and documentation as per cGMP, GLP and at Halewood Lab Pharma Plant. Total responsibility for the Production, Warehousing and other factory management activities at Halewood Lab. Pharma Plant
2.2.4.	Name	:	**Mrs. Ami Dixit**
	Education	:	B.Pharm.
	Designation	:	Sr. Manager - Quality Control
	Experience	:	More than 14 years in Pharmaceutical Industry in Quality control and Quality Assurance.
	Job Responsibility		To monitor the QC function at Halewood Lab. Pharma & Rasna Plant, to seek compliance w.r.t. cGMP and GLP as per regulatory guidelines.
2.2.5.	Name	:	**Mr. Pragnesh Amin**
	Education	:	M.Sc.(Organic)
	Designation	:	Manager – Production
	Experience	:	More than 12 years Experience in Pharmaceutical Industry
	Job Responsibility		To monitor the Production and its function at Halewood Lab.

2.2.6.	Name	:	**Mr. Jitendra Bhati**
	Education	:	M.Com/L.L.B.
	Designation	:	Manager – Finance & Administration
	Experience	:	More than 12 years in imited and P.Ltd. Industry in Finance department
	Job Responsibility		To monitor the Finance function at Complete financial accounting with profit and loss account.
2.2.7.	Name	:	**Mr. Amit Mahida**
	Education	:	B.Com
	Designation	:	Manager – Excise & Distribution
	Experience	:	More than 15 years in Excise & Government related work in Pharmaceutical Industry in Excise department
	Job Responsibility		To monitor the Excise function at Halewood Lab. Pharma & Rasna Plant, to seek compliance w.r.t. cGMP and GLP as per regulatory guidelines.
2.2.8.	Name	:	**Mr. P.S. Jain**
	Education	:	B.Sc.
	Designation	:	Manager – Rasana Food Products
	Experience	:	More than 20 years Experience in food industries & Pharmaceutical Industry in Production department
	Job Responsibility		To monitor the Production function at Halewood Lab. Rasana Plant, to seek compliance w.r.t. cGMP and GLP as per regulatory guidelines.
2.2.9.	Name	:	**Mr. A.S.Shukla**
	Education	:	D.M.E.D.E.E
	Designation	:	Manager – Maitanance
	Experience	:	More than 23 years Experience in food industries & Pharmaceutical Industry in Engineering department.
	Job Responsibility		To monitor the Machinary and its function at Halewood Lab. Rasana Plant,as well as phrama plant.

2.3. Training (Basic & In-Service)

2.3.1. Training needs are identified by comparing the job requirements and the capability of personnel performing the activities. The training needs of personnel are identified by the department In-charges in co-ordination with Quality Assurance Department and accordingly the training programmes are planned.

2.3.2. All new employees undergo an induction program for introduction to the company, key personnel, colleagues and peer groups, policies on health and safety regulations, products and the concepts of Good Manufacturing Practices as well as Good Laboratory Practices.

2.3.3. On - the - job training is undertaken in the respective work area under the guidance of the technical supervisor. Training is also imparted through in-house programs involving classroom sessions and external training programs also.

All operational personnel from Manufacturing, Packaging, Engineering, Stores, QA and QC attend GMP training sessions on regular basis

In service training is imparted to the employees in 3 different modules:

(A) GMP / GLP awareness programs, periodic refresher courses on subjects related to documentation procedures as per Regulatory / Statutory Guidelines.
(B) SOP training and Job related training.
(C) Up-gradation of technical and supervisory knowledge of the personnel with the latest developments in the field of pharmaceutical technology, quality management and supervisory techniques related to administrative skills.

2.3.4. Efficacy of training is assessed through post evaluation of the classroom training by the use of questionnaires with the topic related queries. Department Supervisors regularly evaluate on - the - job performance of staff and workmen by checking work practices, records and day-to-day interaction.

2.3.5. Retraining needs of certain staff and workmen are decided by the concerned Department supervisors as per their on - the - job performance related to the in-house / external training imparted in the department and the classroom. Post evaluation report from the classroom trainers also serve as indicators for re-training of employees.

2.3.6. Training records cover the annual schedule of classroom sessions, the subjects on which training has been imparted, attendance records of the

employees, performance evaluation of the attendees and Re-training Records for certain employees as per requirement.

2.4. Health Requirements for Personnel

2.4.1. Employees health check up is a well organised programmed.

2.4.2. Personnel department is responsible for engaging a well-qualified medical doctor for the medical examination of all employees prior to employment and regularly thereafter.

2.4.3. All employees are routinely checked for their medical fitness and those employees who are advised any medical treatment by the examining doctor, have to undergo the medical treatment as advised.

2.4.4. Departmental supervisors are asked to keep a watch on the health of the personnel working in their areas. Employees are advised to report, incase of any sickness, to their respective supervisor for necessary action.

2.4.5. Employees reported sick couldn't resume duty without certification from the qualified physician about their medical fitness.

2.5. Personnel Hygiene Requirements Including Clothing

2.5.1. The plant has provided suitable washing, changing and rest areas for employees and visitors.

2.5.2. The dress code for employees is suitably decided to meet the requirement of the job they perform. The dress provided for workmen include Shirt, Pant, Cap, footwear and necessary safety appliances.

For female workers, suitable ladies dress is provided taking into consideration the job requirement, GMP and the prevailing culture.

2.5.3. The SOP on clothing clearly describes their routine replacement and laundering. Personnel are positively discouraged from displaying long hair and nails.

3.0 PREMISES AND EQUIPMENT

Premises:

3.1. Description of Manufacturing Areas

3.1.1Plan of the Facility is Attached Separately as Appendix – III

3.1.2This Site has two production buildings:

General Pharma Block-: Drug products of General Pharma Block are manufactured and packaged in this building, with separate processing areas for Tablets & Tablet Packing alongwith the storage of Raw materials, Packaging materials and Finished goods. A self-contained facility for Cephalosporins is provided inside the production block, with separate man and material movement areas.

Isolated Rasna Formulation Block: Dedicated facility for, Isolated Rasna Formulation Block, products on campaign basis mainly solid dosage forms including Instant drink, Powder, Suspensions and Packing with section wise manufacturing and packaging areas alongwith the storage facilities for Raw materials, Packaging materials and finished goods.

3.2Nature of Construction And Finishes

The facility is made of concrete structure, with firm and smooth surfaces, properly coved corners. All fittings and fixtures are flushed. Use of wood and asbestos is avoided in the processing areas.

As per the need of the process, different kinds of flooring have been provided eg.

- Floor with coving
- Polished Kota Stone flooring
- Polished Kota Stone flooring and walls in Isolated Formulation Block.

Material of construction of the doors and windows is suitably painted aluminium with glass, designed so as to have a minimum number of joints and bends.

3.3Brief Description of Ventilation System

Flow Diagrams of HVAC System are covered in Appendix – IV.

The requirement of temperature, humidity and type of air is pre-defined as per the process. Each area is provided according to its environmental requirements, with suitable HVAC Air Handling System.

3.3.1. Specification of Air Supply: Environmental Conditions are specified in the Room program charts and qualified as per area requirements in the HVAC Design Qualification:

For Tablets

Temperature : 25 ± 2°C	Humidity : 50 ± 5%

Pressure differential for Tablets and instant drink are in ascending order from 15Pa in manufacturing area to 30Pa in Quarantine areas, to avoid cross contamination; Min. 25 Air changes per Hr. Air Re-circulation is at 90% with Fresh Air 10% in all the manufacturing areas.

3.3.2. Filter design and Efficiency: Defined in the installation and operational qualification. In all areas, bags of fine air filter (EU-8) efficiency 95% down to particle size 5µ . Pre air filter: 90% down to particle size 10µ. HEPA filter efficiency is qualified through DOP penetration up to limit of 0.01 tests.

3.3.3. Filter is changed if the limit of DOP penetration exceeds the limit 0.01. Filters in oral dosage forms 5µ and 10µ are qualified as per EU guidelines.

3.3.4. Details of area classification, air change rate, filter types room temperature and relative humidity are covered in respective Room Program Charts.

3.3.5. Revalidation of the system is carried out Bi - annually.

3.4 Brief Description of Water System

Schematic diagram of Water System is covered under Appendix-V

3.4.1 Municipality supply water is used as feed water for processing to Purified water

3.4.2 Two water purification systems are provided in the plant: Ion Exchange Plant with capacity of 3.0 M^3 /Hr., and Reverse Osmosis Plant with capacity of 7.3 M^3 /Hr.

3.4.3 Material of Construction of vessels and Pipe work is of SS316.

3.4.4 Filter in the Water System are of 10µ , 5µ and finally of 0.5µ through UV Sanitizer.

3.4.5 Sanitation of pipe work and tanks is performed with Purified Water at 80°C, on weekly basis.

3.4.6 Specification of Purified water produced and used in manufacturing conforms BP (British Pharmacopoeia) Standards.

3.4.7 Sampling points in the manufacturing areas comprise of the user points and also from the Purified Water storage tanks (2 Nos.) Frequency of sampling and testing is scheduled on weekly basis.

3.4.8 Sanitation of pipe work and tanks is performed with Purified Water at 80°C, on weekly basis.

3.5 Maintenance of Premises

Planned preventive maintenance programmed is followed as per SOP which describes in detail the procedure for the manufacturing unit covering the schedule of maintenance and servicing of processing areas, equipment and utilities. Maintenance schedule include daily, weekly, fortnightly and monthly checks and corrective action as per requirement.

SOP covers Preventive and Break down Maintenance of area, equipment and utilities as per calendar and on written intimation from concerned department in charge in the prescribed format. Records of preventive maintenance carried out by the technician and by external agencies, is kept by Engineering department. Machine History Card is filled for major maintenance jobs and modifications, if any.

Maintenance is carried out during weekly of days or during plant / area shut down. So that product quality remains unaffected.

The critical findings from the maintenance reports are made known to the concerned people for timely action as per requirement.

3.6 Brief Description of Major Production and Laboratory Equipment

All equipments have been allotted distinctive Identification numbers. Records for the history of maintenance of critical equipment are kept in the Engineering department.

3.6.1 Machine parts in contact with the drugs products during processing are made of SS 316/316L.

3.6.2 The material of construction for equipment is SS 316/316L.

3.6.3The equipment are designed suitable to operate, clean and maintain, and appropriately located in the operational areas for ease of operation, cleaning and maintenance. The equipment capacity is suited to the batch sizes processed. The equipment are arranged to permit a logical flow of materials.

3.6.4The manufacturing unit is well equipped in each department of the Production Blocks mainly for Production Block-A, for the manufacturing and packaging of Tablet Department. List of Tablet equipments are covered under the lists as follows: This SMF file for Pharma Plant so equipments of Rasna Plant are not included.

3.7.1 (A) List of Critical Equipment in General Block, department wise:

RAW MATERIAL STORES			
Sl. No.	**EQUIPMENT**	**QTY. (In Nos.)**	**FEATURES**
II	**WEIGHING BALANCES :**		Calibrated in-house on daily basis. Certified by Weights and Measures Department, Govt. of India.
1.	Electronic BALANCE 5 Kg	01	Electronic, Digital Balance (Make - Vision)
2.	Electronic BALANCE 120 Kg	02	Electronic, Digital Balance (Make - Vision)
3.	Deep Freezer(2-bdegree)	01	Cut off system (Mangaldeep)
4.	R.A.L.F.	02	SS body.

SITE MASTER FILE

TABLET SECTION

Sl. No.	EQUIPMENT	QTY. (In Nos.)	FEATURES
	Mass Mixer 250 kg	1 No	Code No. Granulation – 1 /01 / 555
	Cadmill	1 No	Code No. Granulation – 1 /02/ 555
	Shifter	1 No	Code No. Granulation – 1 /03 / 555
	Fluid Bed Dryer 200kg	1 No	Code No. Granulation – 1 /04 / 555
	Drum Mixer 400 Kg	1 No	Code No. Granulation – 1 /05 / 555
	Platform Balance 300 kg	1 No	Certified by Weights and Measures Department, Govt. of India. (Make - Vision
	Past Prepparation Vassel	1 No	Code No. Granulation – 1 /07 / 555
	Mass Mixer 100 Kg	1 No	Code No. Granulation – 2 /08 \555
	Multi Mill	1 No	Code No. Granulation – 2 /09\555
	Shifter	1 No	Code No. Granulation – 2 /10 \555
	Fluid Bed Dryer	1 No	Code No. Granulation – 2 /11 \555
	Octagonal Blender 250 Kg	1 No	Code No. Granulation – 2 /12 \555
	P.L.M. 50 Lit	1 No	Code No. Granulation – 2 /13 \555
	Small Sterrar	1 No	Code No. Granulation – 2 /14 \555
	TABLET COMPRESSION MACHINE 23 STN.	1 No	Code No. Compression – 1 /15/555
	TABLET COMPRESSION MACHINE 27 STN.	2 No	Code No. Compression – 2 /16/555
	TABLET COMPRESSION MACHINE 35 STN.	1 No	Code No. Compression – 3 /17/555
	TABLET COMPRESSION MACHINE 35 STN.	1 No	Code No. Compression – 4 /18/555

	TABLET COMPRESSION MACHINE 45 STN.	1 No	Code No. Compression – 5 /19/555
	CONVENTIONAL COATING MACHINE	2 PAN	Code No Coating – 1 / 20/555
	AHU System with DI HUMIDIFIER for Cpmpression	4 Nos	
	AHU System with DI HUMIDIFIER for Packing	5 Nos	
	AHU System with DI HUMIDIFIER for Granulation	2 Nos	
	DUST EXTRACTOR 1 HP	4 Nos	
	Air Condition	4 Nos	
	D.T.Machine	1 No	
	Friability Apparatus	1 No	
	Hardness Tester	1 No	
	Vernier Calipers	2 Nos	
	Platform Balance 300 Kg	1 No	Calibrated in-house on daily basis. Certified by Weights and Measures Department, Govt. of India. (Make – Vision
	Rapid Mixture Granulator 600 liters	01	
	Capsule Filling M/c. S.A.9		Size,2,1 and O
	Tray Drier 100 kg.	01	

Packing Material Store

Sl. No.	EQUIPMENT	QTY. (In Nos.)	FEATURES
	Weighing Balance	1 No	
	WEIGHING BALANCE 6 Kg	01	Calibrated in-house on daily basis. Certified by Weights and Measures Department, Govt. of India. (Make - Vision)

PACKAGING SECTION

Sl. No.	EQUIPMENT	QTY.	FEATURES
	BLISTER PACKING MACHINE 240 Channel	1 Nos	
	BLISTER PACKING MACHINE 150 Channel	1 No	Make : Techno Blist
	STRIP PACKING MACHINE	01	
	CARTON CODING MACHINE	01	
	LABEL CODE PRINTING	01	
	CONVEYOR BELT	5	
	TABLET COUNTERS	Many	Manual, for bulk packing / containerization
	CARTON PACKING MACHINE	01	Adjustable carton folding provision, with PLC (Make – IWKA, VP-120)
	TABET INSPECTION BELT	02	Motor RPM 960 , GB ratio 20:1 (Make – Pharmac)
	Weighing Balance Cap 250 Kg	5	Calibrated in-house on daily basis. Certified by Weights and Measures Department, Govt. of India. (Make - Vision)
	Blister Defoiler	1	
	Strip Defoiler	1	
	FFS pouch packing machine	8	

The facilities / utilities provided at the site are meant for both the Production Blocks, located suitability on the service floor / engineering department, provided through SS-316 L pipelines to the user points in the manufacturing and packing sections, as follows:

FACILITIES / UTILITIES		
Sl. No.	**SYSTEM**	**FEATURES**
	COMPRESSED AIR	Air Compressor GMP Model – Non lubricating Type, Capacity (Make Model :). Air compressor (Make - , Model :) Capacity Air Dryer (Make - Purifier) Capacity. Air Dryer (Make -) Capacity
	DEMINERALISED WATER No.1	DM Water Plant Capacity (Make – Indian ion exchange)
	PURIFIED WATER	RO Plant (Make – Indian Ion Exchange), Capacity 5000 Ltr / day
	BOILER	Capacity (Make) Capacity (Make -)
	ALTERNATE POWER SUPPLY	DG Set Model : (Make -) DG Set Model Make
	EFFLUENT WATER TREATMENT PLANT	Treatment Tanks and facilities for Effluent
	Compressed Air No.2	Air Compressor GMP Model – Non lubricating Type, Capacity (Make Model :). Air compressor (Make - , Model :) Capacity Air Dryer (Make - Purifier) Capacity.

3.7.1(B) Analytical instruments and critical equipment in Quality Control Laboratory:

For Chemical And Instrumental Testing:

Sl. No.	EQUIPMENT	QTY. (In Nos.)	FEATURES
	Analytical Balance 5A Sartorius or Snima Elect.	1	Make : Model: Sr. No
	Analytical Balance 5A Dhona Single Pan Q – 010	1	Make : Model: Sr. No
	Weighing Balance Electro 5A	1	Make : Model: Sr. No
	Refrigerator (with freezer compartment)	1	Make : Model: Sr. No
	Drying Oven [For Dry Purpose]	1	Make : Model: Sr. No
	Drying Oven [For Micro Purpose]	1	Make : Model: Sr. No
	Muffle Furnase Q - 016	1	Make : Model: Sr. No
	Vacuum Oven Q - 011	1	Make : Model: Sr. No
	Vacuum Pump	1	Make : Model: Sr. No
	Water Bath [Thermostatically Controlled }		Make : Model: Sr. No

Sl. No.	EQUIPMENT	QTY. (In Nos.)	FEATURES
	Pentameter [Auto Titractor]	1	Make : Model: Sr. No
	Thin Layer Chromatography	1	Make : Model: Sr. No
	Micrometer	1	Make : Model: Sr. No
	Vernier Caliperse	1	Make : Model: Sr. No
	Sieves [Set]	1	Make : Model: Sr. No
	Ultrasonic Bath [Sonicator)	1	Make : Model: Sr. No
	Microscope	1	Make : Model: Sr. No
	UV Visible Spectrophotometer sA	1	Make : Model: Sr. No
	Polarimeter	1	Make : Model: Sr. No
	Refractometer	1	Make : Model: Sr. No
	PH Meter	1	Make : Model: Sr. No
	Melting Point Test Apparatus	1	Make : Model: Sr. No
	Disintegration Test Apparatus	1	Make : Model: Sr. No
	Dissolution Test Apparatus	1	Make : Model: Sr. No
	Friability Test Apparatus	1	Make : Model: Sr. No
	Karl Fischer Titrator	1	Make : Model: Sr. No
	Mortar with Pestle	1	Make : Model: Sr. No

Sl. No.	EQUIPMENT	QTY. (In Nos.)	FEATURES
	High Performance Liquid Chromatography with Records	1	Make : Model: Sr. No
	Photo flyorimeter	1	Make : Model: Sr. No
	Hardness Tester	1	Make : Model: Sr. No
	Misture Balance	1	Make : Model: Sr. No
	Bulk Density Test Apparatus		Make : Model: Sr. No
	Double Door Autoclave	1	Make : Model: Sr. No
	BOD Incubators (Biological)	1	Make : Model: Sr. No
	BOD Incubators (For fungus)		Make : Model: Sr. No
	Colony Counter with Magnifier	1	Make : Model: Sr. No
	Zone Reader	1	Make : Model: Sr. No
	Centrifuge	1	Make : Model: Sr. No
	Laminar Air flow Bench	1	Make : Model: Sr. No
	Hot Plate	1	Make : Model: Sr. No
	Thermometer (-10 to 110 ^{0} c & 0 to 350 ^{0}c	2	Make : Model: Sr. No
	Weight Box 1 mg to 200 gm	1	Make : Model: Sr. No
	Stopwatch	1	Make : Model: Sr. No
	Conductivity Meter	1	Make : Model:

			Sr. No

3.7.3. A computerized material control system has been provided in the Raw material Stores.
Critical equipment in manufacturing and packaging sections are provided with PLC - Programmable Logical Control, computerized and calibrated for critical indicating parameters viz Temperature and Pressure by Govt. approved external agency with traceability to National laboratories.
Critical analytical instruments are provided with PC and software, with calibration facility for the testing parameters.

3.8 Maintenance of Equipment

3.8.1 The equipment are maintained and serviced by in-house Engineering department and also by external approved agencies for servicing of weighing balances and some analytical instruments.

3.8.2 Services of external agencies are undertaken on contractual agreement between the company and the concerned agency. Annual Maintenance Contract (AMC) is signed for critical process equipment, analytical instruments and utilities.

3.8.3 Maintenance work is carried out without affecting the product quality by scheduling such operations on weekly off days and after working hours. Care is taken to isolate of equipment from materials being processed followed by post maintenance cleaning and lubrication.

3.8.4 Record of routine and breakdown maintenance is kept in Engineering department alongwith records of planned preventive maintenance. Machine history card is updated on completion of maintenance work.

3.8.5 During in-house servicing of process equipment by the Engineering department, observations are notified to the concerned section regarding the nature of service carried out and further precautions to be taken.

3.9 Qualification, Calibration and Validation

3.9.1 A Validation Master Plan has been written, clearly defining the scope of activities such as qualification of equipment, facilities and utilities, validation of processes and analytical methods. The existing products are validated by Concurrent and Retrospective validation methods. Equipments are qualified during commissioning and installation through Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). Standard formats prepared, approved and issued by Quality Assurance Department, are used for Equipment Qualification and Process Validation Studies and Reports. Validation teams are designated to carry out process validations and for analytical method validation. Equipment qualification is carried out by Engineer in presence of authorized production and QA personnel.

3.9.2 Any major change in process equipment is followed by revalidation. Similarly the process is subjected to revalidation, in case of any change. The revalidation of utility services like HVAC System, AHUs, Water System are carried out in case any modification.

3.9.3 Equipment / Instruments of utilities e.g. pressure gauges, temperature indicators, recorders and measuring devices such as electronic balances etc. are calibrated by Government approved agencies / approved external agencies having traceability to the National laboratories. Calibration certificates and reports provided by these agencies are maintained as records of equipment calibration.

3.9.4 Manufacturing process of all products are validated as a part of the Process Validation Programme, taking into account the critical process parameters during manufacturing and packaging of the product as specified in the controlled document - Batch Production and Control Records

3.9.5 Three consecutive batches undergo process validation, after the first commercial batch, which undergoes process optimization. The validation batches undergo detailed testing of the samples collected during the process followed by finished product testing as per specification for data collection and statistical analysis prior to release for commercial distribution

3.10. Sanitation

Cleaning Procedures For Manufacturing Area And Equipment

3.10.1 Standard Operating Procedures for the cleaning of different processing areas are available. SOPs for the cleaning of processing equipment have also been provided.

3.10.2 A schedule for changing of cleaning and sanitizing agents used in the plant has been covered in the respective departmental SOPs, which are strictly adhered to.

3.10..3 The cleaning procedure for areas are validated by the microbiological test method. Cleaning Validation for process equipment is carried out as per protocol by swab testing during product change over. The limit is decided on the basis of Acceptance criteria for the particular drug, to certify the efficacy of the equipment cleaning method used.

3.10.3 Besides validation of the cleaning methods used for area and equipment, random sampling and testing is carried out to monitor its efficacy.

3.10.4 Standard Operating Procedures covering the cleaning methods for the water supply system, air handling system and dust extraction system have been provided alongwith their frequency of cleaning.

4.0 DOCUMENTATION

4.1 Arrangements for the Preparation and Revision and Distribution of Documentation.

The organization has a well designed and comprehensive system of documentation, effectively followed in each department.

4.1.1 Documents governing the functions of each department are maintained in the organization. Standard Operating Procedures (SOP's) are prepared by the related department, reviewed, controlled and issued by Quality Assurance Department. Master Production and Control Record (MPCR) and the Batch Production and Control Record (BPCR) are prepared by the Formulation Development Department of Ipca Lab. Or Makers Lab. Reviewed by Production department, reviewed, controlled and issued by Quality Assurance. Specifications of raw materials, packaging materials, in process and finished products are prepared controlled and issued to Quality Control Department.

4.1.2 Quality Assurance department as responsible for the preparation, revision and distribution of the technical documents.

4.1.3 The master documents are stored in the Quality Assurance Department.

4.1.4 Standard Operating Procedure for the preparation of SOP and other technical documents specifies the size and colour of paper and the format to be used for each type of document. Documents controlled the Quality Assurance and Quality Control department include:

1. Standard Operating Procedures (SOP's).
2. Raw Material Specifications.
3. Packaging material Specifications.
4., In-process Specifications.
5. Finished Product Specifications.
6. Method of Analysis (with each specification).
7. Master Production and Control Records.
8. Batch Production and Control Records.
9. SOP for Release for Finished Goods.

4.1.5 All technical documents are computerized with access to Quality Assurance Department only. The master documents are preserved by the Quality Assurance Department. The documents issued to the concerned department are duly signed, stamped as "Controlled Documents" and issued by Quality Assurance Department.

4.1.6 The Batch Production and Control Records including its Certificate of Analysis are preserved for a period of one year beyond the expiry of product as per statutory requirements.

4.1.7 The documents are preserved as hard copies only and not electronically at present.

4.2Other Documentation Related to Product Quality

The other documents available and in use, are as follows:-

1. Equipment Qualification (DQ, IQ, OQ & PQ).
2. Standard Operating Procedures.
3. Quality Control Procedures.
4. Training Procedure.
5. Process Deviation Reports.
6. Calibration Certificates and Records.
7. Process Validation Protocols and Reports.

4.3 Additional Documentation

1. Planned Preventive Maintenance Records
2. Medical Check up and Health Records
3. Pest and Rodent Control Records.

5.0 PRODUCTION

Flow diagram of Pharmaceutical process- Appendix - IV

5.1 Brief Description of Production Operations

Production operations are carried out under the supervision of qualified and experienced technical staff, graduates / postgraduates in Pharmacy / Chemistry with experience in pharmaceutical production. Supervisory staff is trained to be always vigilant during the processing activities. In-process Quality Control monitors the batch processing. The BPCR is recorded as the batch manufacturing progresses and reviewed by QA at every stage. Batch manufacturing is carried out as per the respective BPCR, replica of the MPCR. Batch reconciliation is done at critical stages of manufacturing and packaging. The dosage forms produced at this location are (a) Uncoated and (b) coated tablets. The production flow charts are appended to this Site Master File.

5.2 Handling of Materials During Production

Raw materials and Packaging materials received, are verified for approved vendor, identified by the suppliers lot number and then quarantined. Sampling by QC Chemist is carried out as per sampling plan for the particular item i.e. active ingredient, excepient or the packaging component and allotment of A.R. No. (Analytical Report Number). The sample is taken to the Quality Control for laboratory for analysis as per its specifications and approved / rejected subject to its conformance. On QC approval, under test material is transferred to the approved area after changing its label status.

The materials are labeled as Sampled / Under Test / Approved / Rejected as per their status.

Approved Raw materials and Packaging materials are issued to Production on Dispensing Sheet of the BPCR. Raw materials are weighed on calibrated weighing balances of suitable capacity by the authorized Stores personnel in presence of Production personnel.

5.2.1 **Control of Bulk Manufacture**
Critical parameters of manufacturing are checked by production personnel. IPQC also checks the parameters during manufacturing as per BPCR. In process checks are recorded and the observations notified to production for necessary action.

5.2.2 **Packing**
Semi finished products are analyzed by Quality Control Laboratory as per specification. Pooled samples are sent for this purpose from the in process checked the sample by IPQC. On conformance, the bulk samples are allowed for packaging operations on written intimation to production department. Line clearance checks are performed by production personnel and verified by QA as per checklist, for commencement of packaging operations.

5.2.3 The packed finished goods are quarantined till approval by QC after complete analysis. Finished goods are released by QA for final marketing and distribution, after auditing the BPCR and confirmation of the Batch Reconciliation.

5.2.4 All production, Quality Control and Quality Assurance operations are supervised by the technically qualified personnel certified by the FDA authorities of the State Government.

5.3 Reprocessing / Rework

SOP for reprocessing / rework details the procedure for addition of recoverable residues upto 10% of the batch size under manufacturing of solid dosage formulations.

5.4 Handling of Rejected Materials

Materials not complying with specifications / norms are labeled as “Rejected” by QC and stored under lock and key till their disposal.

5.5 Process Validation

Products undergo process validation prior to commercial distribution. After technology transfer from F & D Department to the Plant, the first batch undergoes process optimization. The following three batches are validated for all critical process parameters during manufacturing as per Protocol issued by Quality Assurance Department. The validation team consists of responsible personnel from F & D, Production and Quality Assurance and Quality Control Departments. The data of the three batches validated, is compiled and evaluated statistically to check the relative standard deviation. Once the report is found within the pre-decided limits,

the process validation studies are approved by Quality Assurance Manager.

6.0 QUALITY CONTROL

6.1Quality Control System

Quality control department functions as per Standard Operating Procedures (SOPs) by which all its activities are governed. The sampling and testing of starting materials - raw and packaging materials, the in-process materials like blends and granules and the finished products in the packaged form are activities carried out by the authorized personnel i.e. Quality Control Chemists as per approved specifications. Each batch undergoes individual sampling and testing prior to approval / rejection. The despatch of finished goods for sale / distribution can be planned only after authorization for Release after approval by Quality Control department.

6.1.1 Activities of Quality Control Department

The raw material, packaging components, semi finished goods and the finished products are sampled as per SOP. These items are analyzed by Standard Test Procedures and approved on compliance to specifications. SOPs, Specifications and Test Methods constitute the documents controlled, issued and used by the Quality Control Department for the sampling, testing and approval of materials and products.

The methods of analysis used by Quality Control Department cover physical and chemical testing, instrumental analysis by sophisticated electronic instruments viz UV / Visible Spectrophotometer, Gas Chromatograph (GC), High Pressure Liquid Chromatograph (HPLC), and microbiological testing for total bacterial count, fungal count and absence of pathogens.

The test results are documented and preserved as Certificate of Analysis with the raw data, as per statutory requirements upto one year beyond the expiry of finished products.

6.1.2 The batch history is recorded in the BPCR - Batch Production and Control Records, from its issue till the packaging and despatch of the finished goods, Each BPCR is issued to Production department by Quality Assurance and is reviewed during dispensing, manufacturing, packaging and during the release of the finished product. Certificate of analysis is prepared on completion of testing

of finished product and enclosed in the BPCR by Quality Control Department.

6.1.3 Specifications for raw materials, packaging components, in process items and finished products are prepared by Quality Control Department, approved and controlled by Quality Assurance. SOPs are prepared by the respective departments, reviewed, approved and controlled by the Quality Assurance department. The Batch Production and Control Records (BPCR) are prepared by the Production Department based on the transfer of technology from R&D department to the manufacturing unit. These are reviewed, controlled and issued by Quality Assurance Department. Master documents are preserved in the Quality Assurance Department.

7.0 CONTRACT MANUFACTURE AND ANALYSIS

The audit of the contract manufacturer is carried out on the lines of the SOP for Self-inspection which details the procedure to carry out the GMP Audit of the manufacturing unit. Thereby, the contract acceptor is bound to comply with the GMP requirements during all stages of the batch processing at their premises.

The contract is signed between the company and the acceptor after the total assessment of facilities, capacity utilization, systems and documentation in place at their manufacturing unit. Subsequently, the facility is audited as per the decided frequency and as per requirement.

8.0 DISTRIBUTION, COMPLAINTS AND PRODUCT RECALL

8.1 Storage and Distribution Practices

A well defined system for the distribution of finished products is detailed in the SOP and stringently followed. The dispatches are recorded manually and by computerized system as well, clearly specifying the quantities dispatched to the different destinations through the Sales Depots.

8.1.1 A highly secured and well-constructed warehouse for the storage of the finished goods for distribution, forms part of the Production Block.

8.1.2 The storage conditions in the warehouse are maintained as per the requirement of the products i.e. room temperature storage and low temperature / low humidity storage.

8.1.3 Presently, none of the products requires refrigerated storage

8.1.4 The products packed in corrugated boxes as transferred from the packing

department, are stored on clean PVC pallets avoiding any direct contact with the floor.

8.1.5 The finished product shippers are appropriately labeled with the details of Product name, Batch number, Date of manufacturing and Date of expiry, which help in proper identification. Returned materials, if any, isolated and stored under lock and key in the designated area.

8.1.6 Distributions of products to customers are through a supply chain. Finished goods are transferred from the manufacturing site and distributed through the network of Sales Depots of Ipca Lab. Ltd or Makers Lab. Ltd across the country, whereby the stocks are received by the stockiest and distributors appointed by the company in different cities of some states. Retailers / chemist - dispensing pharmacist receive the goods from the stockiest / dealers and then sell the products to the customers on as per the medical practitioner's prescription.

The products also reach the customers through the dispensing pharmacist at Government hospitals to which the company's products are supplied from the Sales Depots as per the Government orders booked in advance, and identified separately.

8.1.7 The finished goods are distributed as per the requisition orders of Ipca Lab. Ltd or Makers Lab. Ltd or any other concerned Company for ehom job work is carried out in the premises on first in – first out (FIFO) basis.

8.2 Records of Distribution

Distribution record is maintained and reconciled on complete distribution of the batch. The distribution details include the name of purchaser, destination, date of sale, quantity dispatched and other commercial information. Historical distribution details, product and batch wise, are retrievable immediately.

8.2.1 Complaints

8.2.1.1 Market complaints are normally raised by doctors, consumers, Medical Representatives or FDA officials.
The SOP on Handling of Market Complaints includes the following points:

1. Receipt of the complaint and its verification for genuineness, nature of complaint and complainant's details.

2. Recording the available information about the product under complaint, its batch number and the details evaluated and verified.

3. Comparison with the retained sample of the product and batch number, by

parallel analysis in our Quality Control Laboratory.

4. Review of BPCR for manufacturing and packaging details alongwith the initial Certificate of Analysis.

5. Identify the reasons for the complaint and prepare its report, to be informed to the marketing department of Ipca Lab. through the medical division, for the complainant, as decided.

6. Take corrective action according to the nature of complaint.

7. Record completely the investigations and action taken in the Complaint file maintained in the Quality Assurance Department.

8.2.1.2 Market complaints are received by the Quality Assurance Manager and then recorded by his deputee as per the department procedure based on SOP.

8.2.1.3The report of the market complaint received by the Quality Assurance Department, is prepared after complete investigation, analysis and evaluation by the Production Manager and Quality Assurance Manager.

8.2.1.4 Quality Assurance Manager and the Works Manager review the complaint reports, prepare a summary the corrective actions taken, and submit to the Senior Management.

8.2.1.5 The market complaint records are kept for a period of one year beyond the expiry of the finished products.

8.2.2 Product Recalls

8.2.2.1 Product recall, if required, is carried out as per SOP. It clearly states the actions to be initiated for recalling a product. The distribution data are immediately retrieved to note the destinations to which the quantities were dispatched. The returned product is inspected thoroughly for intactness of the packs on receipt and stored under lock and key in a segregated manner. After complete investigation, the report is prepared by the Quality Assurance Manager and jointly reviewed with the Works Manager, on confirmation of the cause for recall. The Distribution Incharge in consultation with Quality Assurance Manager and Works Manager initiates corrective actions.

8.2.2.2 The Distribution Manager at the manufacturing site is responsible for co-ordinating the product recalls.

8.2.2.3 The Chief Executive - Quality Assurance notifies the FDA Authorities, as per requirement, based on the reason for the product recall.

8.2.2.4 The local FDA Authorities, may involve in the procedure, as per their discretion.

8.2.2.5 Since distribution records indicate traceability, the recall can be affected upto the whole sale and retail level.

9.0 SELF INSPECTION

9.1 Self-inspection is carried out as per SOP covering Production, Quality Control Laboratory, Quality Assurance Stores of raw materials, packaging materials and finished goods, Engineering department and Personnel department are covered under the self-inspection programme as scheduled in its calendar.

9.1.1 The Self-inspection system is carefully designed by the Quality Assurance Manager in consultation with the Department Heads and the Works Manager, in order to seek overall compliance as per cGMP for systems, documentation and work practices. Each audit is planned by the audit team consisting of the Quality Assurance Manager and the Department Incharge. The Self Inspection may be carried out a surprise manner without pre intimation, to check the compliance to SOPs.

9.1.2 The efficacy of the Quality Systems implemented in the manufacturing unit, become evident on Self Inspection as the works practices and records are reviewed thoroughly for their compliance to SOPs, specifications and the batch manufacturing and packaging records.

9.1.3 Self-inspection is carried out as per its SOP, which elaborates the instructions to be followed by the audit team, as per the current regulatory guidelines. The format for Self-inspection and its response on a standardized format for the Audit Response, is appended in the SOP.

9.1.4 The Self-inspection report is documented and circulated to Department In-charges with a copy to the Works Manager. Action plan is prepared by the concerned Department Incharge in response to the points raised in the Self-inspection report, subsequent to the agreement between the responsible personnel during the concluding meeting.

9.1.5 The SOP on Self-inspection specifies the time limit required for the response of the audit points. Time frame for the corrective actions to be taken has to be mentioned in the Audit Response Sheet. These reports are reviewed regularly for improvement and compliance.

***