1.1 Brief information of the firm

BetaMax Remedies Pvt. Ltd. was established in the year Jan 1996 and managed by professional board of directors. Since then the Company is into formulation. Previously running only with capsule section at Punchkulla, now in year 2008 established a G.M.P. Unit at village Tahliwal, Site address of which is as under :

Name and address of the company
BETAMAX REMEDIES PVT LTD.
PLOT NO :- 24-25,
INDUSTRIAL AREA, PHASE – 1 & 2
TAHLIWAL
Dist. UNA (Himachal Pradesh)
India.

1.2 Pharmaceutical manufacturing activities:

At the above address the company will manufacture Solid Oral Dosage form (Viz. Tablets and Hard Gelatine Capsules), Liquid oral dosage form and External applications (Viz. Liquids and Lotions)

1.3 A Short Description Of Site:

Location and immediate environment
About 10 km from Bhakhara Nangal on Nangal-Garhshankar Road, situated in semi hilly area, in pollution free environment and excise free zone

Size of the site Plot	:	2500 sq. meters
Built up	:	1300 sq. meters
Production	:	660.57 sq. meters (Ground floor)
	:	48.25 sq. meters (First Floor)
QC Area	:	92.57 sq. meters
Adm. Area	:	26.42 sq. meters
Warehouse (Stores)	:	132.47 sq. meters
Utility Block	:	134 sq. meters
Security Block	:	32.69 sq. meters
Corridor & Loading plateform	:	93.46 sq. meters
Unloading Plateform	:	14.28 sq. meters

Only Pharmaceutical operations are carried out in the premises.

1.4 Number of employees engaged in Production, Quality Control, Storage and Distribution, Engineering and support services

Production	:
Quality control and Quality Assurance	:
Storage and distribution	:
Technical and engineering	:
Administration	:
Total	:

1.5 Use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis :

Our Quality Control facilities are self sufficient and well modernized and we do not rely on out side testing facilities except for very specific tests that cannot be carried out at the site.

1.6 Quality Management System is governed by

1.6.1 Quality Policy

1.6.2 Environment, Health and Safety policy

1.6.3 Responsibility of Quality Assurance Functions

- Quality Assurance department is responsible for compliance of CGMP at all levels and in all the departments.
- Monitoring of Quality system through trend analysis and Annual product review etc.
- Reviewing and approval of master documents like standard operating procedures, batch records, validation protocols and reports etc.
- Handling of market complaints and product recalls.
- Issuance and control of quality related documents like standard operating procedures, batch records, specifications and standard operating procedures.
- The final “Release for Sale” is done by the QA, after reviewing all batch data and Certificate of Analysis of the product.

1.6.4 Organization structure

1.6.5 Audit Programs :

There is a written procedure and program for Self-inspection

1.6.6 Review of results :

Results are reviewed at all critical stages of manufacture and testing by Quality assurance personnel.

1.6.7 Supplier's assessment :

Critical suppliers are assessed as per the requirements of the company, with respect to quality.
Assessment of suppliers of critical raw materials and packing materials is achieved through regular audits of the parties & follow-up audits or through review of satisfactory vendor assessment questionnaire.

2 PERSONNEL

2.1 Organization chart for Quality Assurance, Production, and Quality Control:

2.2 Qualification, experience and responsibilities of key personnel :

2.3 Training:

- Induction training programs are organized for new employees whereby they are introduced to the company and its products, health, hygiene and safety regulations; GMP guidelines and statutory requirements.
- On – the – job training is conducted by trained personnel.
- Periodic training on various aspects like unit operations and processes, use of equipment, plant safety , Health & Hygiene and cGMP are carried out by in-house as well as outside specialists.
- Staff members regularly participate in national and international seminars, training programs and workshops as part of their continuing education.
- Information obtained through performance reviews, self-inspections and audits forms the basis for identifying areas of retraining.
- Records relating to training and post –training assessment are maintained.

2.4 Health Requirements for Personnel Engaged in Production :

- Head, Plant Personnel is responsible for checking health of employees through the medical doctors.
- All employees are medically examined at the time of recruitment.
- Routine medical examination of all employees is carried out by a qualified professional on regular basis.
- Personnel suffering from illness such as skin rashes, colds, communicable diseases, cuts or open lesions to the body surfaces are required to report the same and are excluded from working in the critical areas.
- After illness, Employee has to produce fitness certificate duly certified by a registered medical practitioner.
- Staffs who are working in Critical Area, are checked for any signs of contagious disease.

2.5 Personnel Hygiene :

- Suitable washing, changing and rest areas are provided.

- Staff wears factory uniform appropriate to the area they are working. Persons who are working in the manufacturing area and are directly coming in contact to the products have to wear boiler suit, cap, footwear provided by the company

- There are Standard Operating procedures for entry / exit of employee in manufacturing area, packing area. There is separate Standard operating Procedure for entry / exit of visitor in manufacturing area, packing area

- Eating, drinking, tobacco chewing and smoking are prohibited in the manufacturing area.

3 PREMISES AND EQUIPMENT

3.1 Premises :

Ref. to Annexure: (AA)

3.2 Nature of Construction and Finishes :

Buildings are constructed with bricks and RCC structure with Kota stone floorings, jointing of flooring is done by epoxy, Inside walls are plastered to smoothness and painted with epoxy paint. Dead ends are taken care off by coving

The ceilings in the manufacturing areas are ferroconcrete plaster to smoothness and appropriate (Calcium Silicate) false ceiling and painted with washable epoxy paint.

All lighting in the process areas is either recessed or enclosed.

3.3 Brief Description of Ventilation System :

There is schematic ventilation systems in the manufacturing areas. Air-conditioning is provided for all the processing area through eleven air conditioners There are fifteen different Air Handling Units for manufacturing area and QC, which will

maintain RH and temperature There are eight fresh air units for bottle washing and changing rooms

Manufacturing areas :

Centralized air-conditioning is provided in this area. Air in this area is filtered through series of filters and finally through 0.3 □ filters provided at plenum. Dust extraction system has been provided in compression areas. Temperature is maintained at comfort condition.

Air conditioning system for production rooms, dispensing rooms sampling rooms, internal corridors, and air-locks are maintained at different pressure to avoid mixing or air from different rooms and sections, Maintenance of pressure is monitored by megnehelic gages. Actual weighing of active materials and excipients are carried out under reverse Laminar Air Flow Cabinet.

S.NO.	NAME OF EQUIPMENTS	CAPACITY	EQUIPMENT ID
1	SAMPLING BOOTH	------	A/2008/WH/01
2	DESPENSING BOOTH	-------	A/2008/ WH /02
3	WEIGHING BALANCE	300 GMS	A/2008/ WH /03
4	WEIGHING BALANCE	1.5 KG	A/2008/ WH /04
5	WEIGHING BALANCE	3 KG	A/2008/ WH /05
6	WEIGHING BALANCE	15 KG	A/2008/ WH /06
7	WEIGHING BALANCE	30 KG	A/2008/ WH /07
8	WEIGHING BALANCE	75 KG	A/2008/ WH /08
9	WEIGHING BALANCE	150 KG	A/2008/ WH /09
10	WEIGHING BALANCE	600 KG	A/2008/ WH /10

3.4 Handling of Highly Toxic Hazardous and Sensitizing Materials.

No highly toxic Hazardous and Sensitizing materials are handled at this site.

3.5 Brief Description of Water Systems :

Government supply water is first stored in 40,000 litters under ground R.C.C. Storage tank. Water is uplifted on top floor to 3000 litters capacity tanks and then processed through R.O. System. Purified water is stored in purified water storage tank of S.S. 316, material and then circulated through Purified water loop system of S.S. 316 material into production area. Purified water is maintained above 60□C.

Water is tested as per IP / BP.

Purified water –

Total Bacterial Count NMT 100 CFU/ml
Pathogens should be absent.

There are designated sampling points and samples are taken at Pre - decided intervals.

Sanitation of the water system and loops is carried out according to standard operating procedures.

3.6 Planned Preventive Maintenance Program :

- There is a planned preventive maintenance and servicing program for all equipment and utility systems.
- Service Cards and Preventive Maintenance checklist are filled while doing preventive maintenance for individual equipment Records are kept for reference purpose.

3.7 Production and Control lab Equipment :

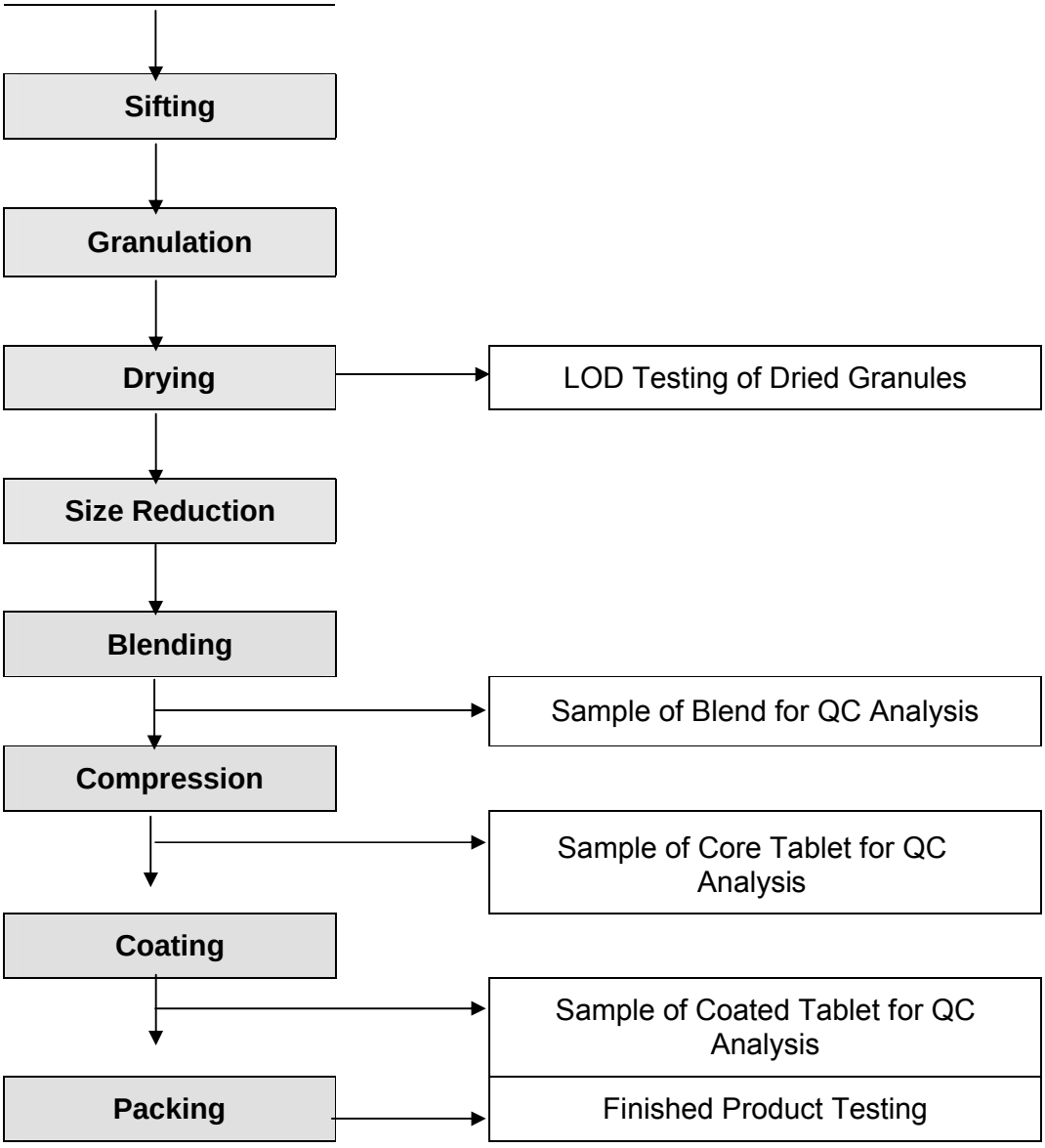
3.7.1 Tablet :

Sifted materials are mixed/granulated through Mass Mixer. The wet granules are dried using FBD. The dried granules are sized using an oscillating granulator/multimill. The contact parts of the sifters, Mass Mixer, FBD and OG/Mill are of SS 316.

Sized Granules are lubricated in Rotocube Blender made up of SS 316.
Lubricated granules are compressed using rotary compression machines.Film coating is done in conventional coating pan made up of SS 316. Coating system including coating gun, S.S. stand, automatic peristaltic (spray) pump, 25 lts S.S. container. Tablets are packed on blister / strip packing machines.

FLOW CHART OF TABLETS SECTION

Dispensing of Raw Material


Sifting
Granulation
Drying
LOD Testing of Dried Granules
Size Reduction
Blending
Sample of Blend for QC Analysis
Compression
Sample of Core Tablet for QC Analysis
Coating
Sample of Coated Tablet for QC Analysis
Packing
Finished Product Testing

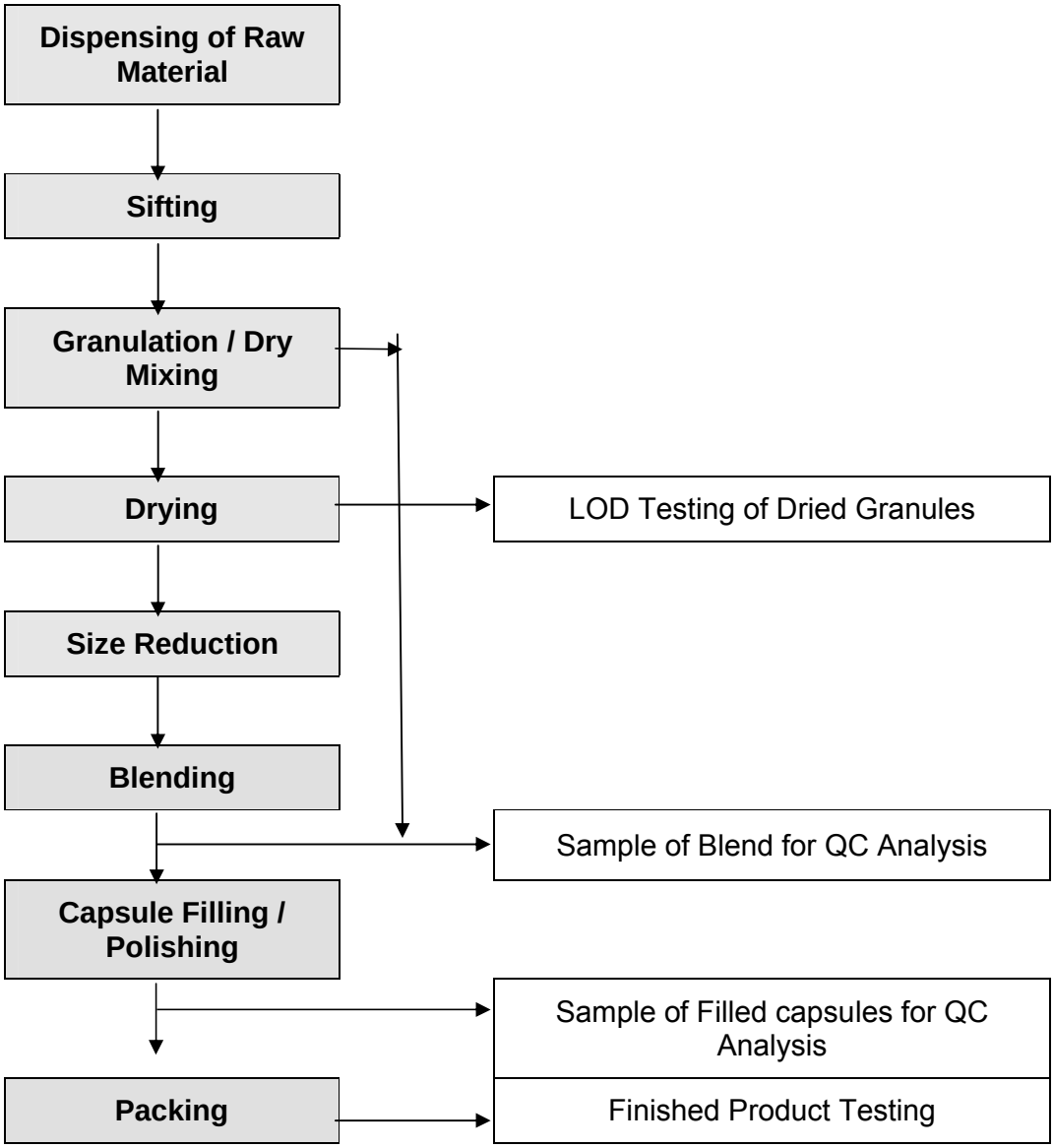
LIST OF TABLET MACHINERY

S.No.	Description	Capacity	Equipment ID
1.	Tablet Machine no 1	20 station	A/2008/TB/001
2	Tablet Machine no 2	27 station	A/2008/TB/002
3	Double layer attachment for Machine 2	----	A/2008/TB/003
4	Round shape dies & punches	----	A/2008/TB/004
5	Capsules shape dies & punches	----	A/2008/TB/005
6	Fluid bed drier 60 kg	60 kg	A/2008/TB/006
	A) Extra silicon gasket	----	A/2008/TB/007
	B) Extra bags	----	A/2008/TB/008
7	De-burring/De-dusting units	----	A/2008/TB/009
8	Dust Extractors	----	A/2008/TB/010
9	Multi mill	----	A/2008/TB/011
10	Sifter	30 inch	A/2008/TB/012
11	Table Hardness Tester	----	A/2008/TB/013
12	Mass mixer	100 kg	A/2008/TB/014
13	Coating Machines	36 inch dia	A/2008/TB/015
14	Oscillating granulatór	50 kg	A/2008/TB/016
15	Tablet inspection belt	----	A/2008/TB/017
16	Paste Kettle	50 kg	A/2008/TB/018
17	Roto cube Blender	100 kg	A/2008/TB/019
18	Coating system (Spray Gun and Pump)	----	A/2008/TB/020

3.7.2 *Hard Gelatin Capsules :*

Sifted Raw materials are blended in Double Cone Blender made up of SS 316. This is filled in E G Capsules using semi-automatic filling machine. Followed by automatic polishing of capsules.
Capsule packing is done on strip packing machine/blister packing machine.

FLOW CHART OF CAPSULE SECTION



LIST OF CAPSULE MACHINERY

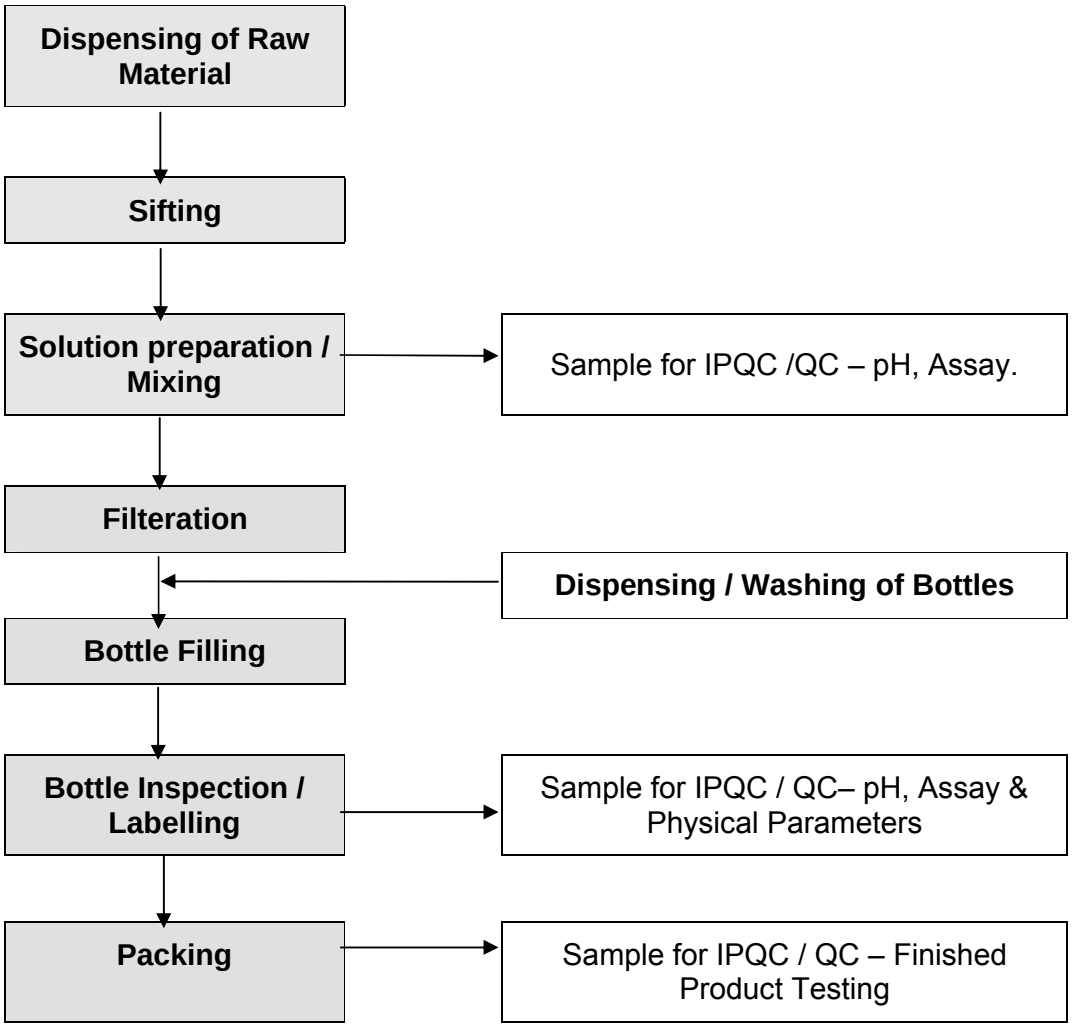
S.No.	Description	Capacity	Equipment ID
1	Double Cone Blender.	100 kg	A/2008/CP/001
2	Sifter	30 inch	A/2008/CP/002
3	Semi-Auto capsule Filling Machine	S-A- 9	A/2008/CP/003
4	Vacuum pump	----	A/2008/CP/004
5	Feeder Sorter	----	A/2008/CP/005
6	Dedusting and polishing machine	----	A/2008/CP/006
7	Compact Air displacement unit	----	A/2008/CP/007
8	Empty capsule sorter	----	A/2008/CP/008

3.7.3 Oral Liquid:

After dispensing the material to the first floor of the production area, Sugar Syrup preparation, liquid mixing and manufacturing is done in jacketed sugar syrup vessels and manufacturing vessels made up of S.S. 316 material. Bottles are washed in

automatic rotary bottle washing machine. Washed bottles are transferred to automatic four head bottle filling machine, Manufactured material in first floor after passing through filter press of S.S. 316 material contact parts is stored in storage vassal made of S.S. 316 material and then transferred to ground floor by gravity to automatic four head filling machine. After filling bottles are first inspected and then before packing labelled by automatic sticker labelling (Self Adhesive) machine. The flow chart is as under:

FLOW CHART OF LIQUID ORAL SECTION



LIST OF LIQUID LINE MACHINERY

S.No	Discription	Capacity	Equipment ID
1	Horizontal Filter Press	----------	A/2008/OL/001
2	Colloid Mill	----------	A/2008/OL/002
3	Transfer Pump	----------	A/2008/OL/004
4	Sugar syrup vessel	600 liters	A/2008/OL/005

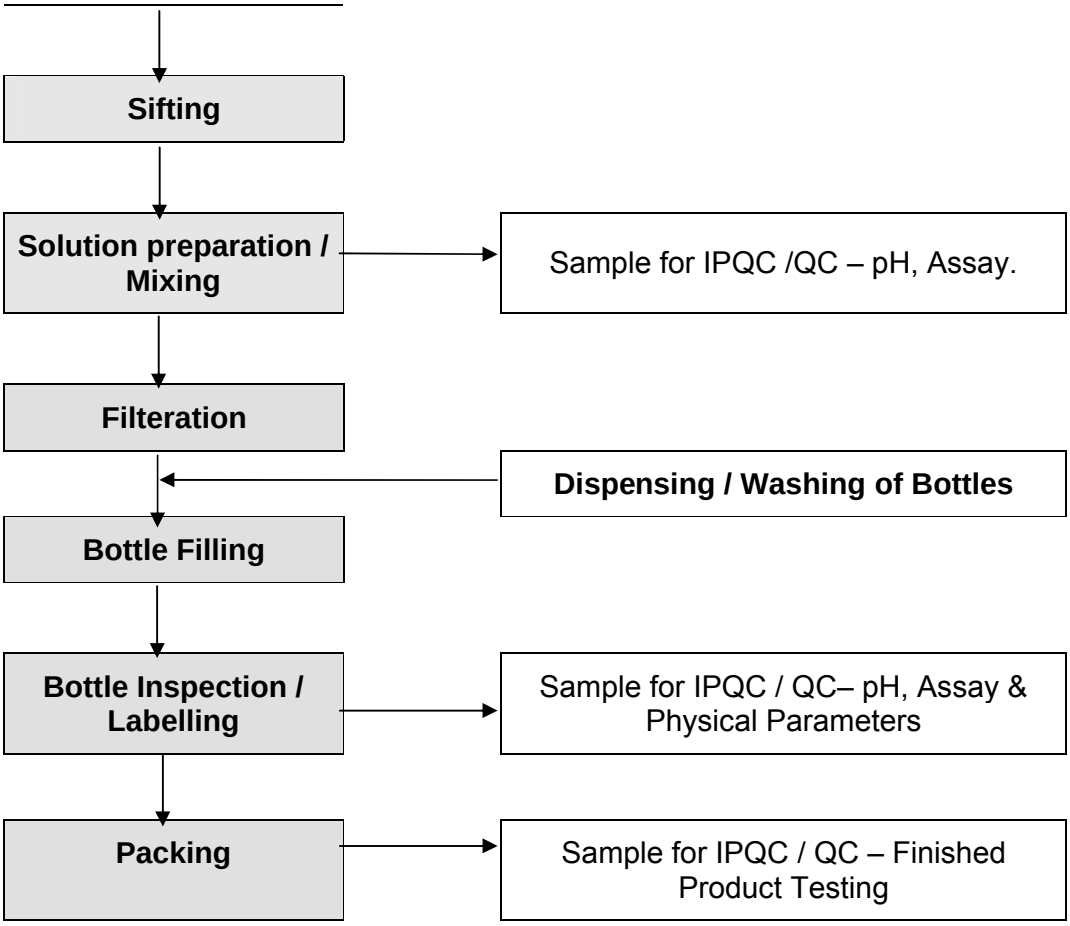
5	Manufacture. vessel 1200 Us.	1200 liters	A/2008/OL/006
6	Storage vessel	1200 liters	A/2008/OL/007
7	SS Piping/Control Panel	----	A/2008/OL/008
8	SS storage tanks 50, lts	50 liters	A/2008/OL/009
9	SS storage tanks 100 lts	100 litters	A/2008/OL/010
10	SS storage tanks ,200 lts	200 liters	A/2008/OL/011
11	Automatic Bottle washing machine	-	A/2008/OL/012
12	Turn Table - 36"	-	A/2008/OL/013
13	Automatic filling machine	four head	A/2008/OL/014
14	Pre-nitrogen flushing machine		A/2008/OL/015
15	Automatic sealing machine	four head	A/2008/OL/016
16	Online bottle inspection machine		A/2008/OL/017
17	Automatic sticker labeling machine		A/2008/OL/018
18	Hot foil batch printing device		A/2008/OL/019
19	Packing conveyor belt		A/2008/OL/020

3.7.4 External Applications

After dispensing the material to production area, liquid/lotion mixing and manufacturing is done in jacketed vessel contact parts made up of S.S. 316 material. Bottles are washed in automatic rotary bottle washing machines. Washed bottles are transferred to automatic four head bottle filling machine, manufactured material is first stored in storage vassal made of S.S. 316 material and then transferred to automatic four head filling machine. After filling bottle are first inspected and then before packing labelled by automatic sticker labelling (Self Advise) machine. The flow chart is as under:

FLOW CHART OF EXTERNAL APPLICATION SECTION

Dispensing of Raw Material



LIST OF EXTERNAL APPLICATION MACHINERY

	Description	Capacity	Equipment ID
1	Horizontal Filter Press	----------	A/2008/ EA /001
2	Colloid Mill	----------	A/2008/ EA /002
3	Transfer Pump	----------	A/2008/ EA /004
4	Manufacturing vessel	500 liters	A/2008/ EA /005
5	Manufacture vessel (Jackated Vessel)	200 liters	A/2008/ EA /006
6	Storage vessel	500 liters	A/2008/ EA /007
7	SS Piping/Control Panel	----	A/2008/ EA /008
8	SS storage tanks 50, Its	50 liters	A/2008/ EA /009
9	SS storage tanks 100 Its	100 litters	A/2008/ EA /010
10	SS storage tanks ,200 Its	200 liters	A/2008/ EA /011
11	Automatic Bottle washing machine	_	A/2008/ EA /012
12	Turn Table - 36"	_	A/2008/ EA /013
13	Automatic filling machine	four head	A/2008/ EA /014
14	Automatic sealing machine	four head	A/2008/ EA /016
15	Online bottle inspection machine		A/2008/ EA /017

16	Automatic labeling machine		A/2008/ EA /018
17	Hot foil batch printing device		A/2008/ EA /019
18	Packing conveyor belt		A/2008/ EA /020

3.7.5. Packing

Packing is done under Comfort air maintaining the temperature. Strip packing and Blister packing is done under separate AHUs maintaining RH and Temperature, Pressure in the rooms are maintained by megnehelic gages.

	Description	Capacity	Equipment ID
1	Horizontal Filter Press	----------	A/2008/ PK /001
2	Blister packing Machine	----------	A/2008/ PK /002
3	Conveyer belt	----------	A/2008/ PK /003
4	Conveyer belt	--------	A/2008/ PK /004
5	Weighing balance	30 kg	A/2008/ PK /005
6	Weighing balance	150 kg	A/2008/ PK /006
7	M.S. Pallet truck		A/2008/ PK /007
8	M.S. Pallet truck		A/2008/ PK /008

3.7.5 Quality control :

Analysis is performed on input material, intermediates, and finished products using classical analytical “wet chemistry” techniques as well as sophisticated instrumentation such as HPLC, and UV spectrophotometer. The laboratory is also provided with the necessary equipment including incubators, laminar airflow units for microbiological testing. In production section, there is a separate IPQC lab for in process testing.

LIST OF LAB MACHINERY

SR. NO	NAME OF EQUIPMENTS	EQUIPMET ID
1	DISSOLUTION STRENGHT TEST APPARTORS	A/2008/QC/001
2.	KARL FISCHER AUTO TITRATOR	A/2008/ QC /002
3.	MELTING/BOILING POINT APPARATUS	A/2008/ QC /003
4.	BULK TENSITY APPARATUS	A/2008/ QC /004
5.	DISINTEGRATION TEST APPARATUS	A/2008/ QC /005
6.	FRIABILITY TEST APPARATUS	A/2008/ QC /006
7.	LEAK TEST APPARATUS	A/2008/ QC /007
8.	IR MOISTURE BALANCE 10 GRAM	A/2008/ QC /008
9.	VACCUME OVEN	A/2008/ QC /009
10.	VACCUME PUMP	A/2008/ QC /010
11.	WATER BATH DOUBLE WALLED	A/2008/ QC /011
12.	CENTRI FUGE MACHINE	A/2008/ QC /012
13.	HOT AIR OVEN	A/2008/ QC /013
14.	HOT AIR OVEN	A/2008/ QC /014
15	MUFFLE FURNACE	A/2008/ QC /015

16.	FUMEHOOD SS	A/2008/ QC /016
17.	HEATING MENTEL	A/2008/ QC /017
18.	CONDUCTIVITY METER	A/2008/ QC /018
19.	REFRACTOMETER	A/2008/ QC /019
20.	HEATING PLATE	A/2008/ QC /020
21.	BOD INCUBATER (AUTOMATIC)	A/2008/ QC /021
22.	BIOLOGICAL INCUBATER OR BACTERIOLOGICAL INCUBATER	A/2008/ QC /022
23.	DIGITAL COLONY COUNTER	A/2008/ QC /023
24.	ANTIBIOTIC ZONE READER	A/2008/ QC /024
25.	AUTO CLAVE (VERTICAL) LAB MODEL	A/2008/ QC /025
26.	AUTO CLAVE (VERTICAL) LAB MODEL	A/2008/ QC /026
27.	STABALITY CHAMBER OR ENVIORMENTAL CHAMBER	A/2008/ QC /027
28.	STABALITY CHAMBER OR ENVIORMENTAL CHAMBER	A/2008/ QC /028
29.	HORIZENTAL LAMINAR FLOW	A/2008/ QC /029
30.	WEIGHING BALACE 220 GM(INTRENAL CALIBRATION)	A/2008/ QC /030
31.	WEIGHING BALACE 220 GM(EXTERNAL CALIBRATION)	A/2008/ QC /031
32.	WEIGHING BALACE 220 GM(EXTERNAL CALIBRATION)	A/2008/ QC /032

3.8 Maintenance of equipment:

- Maintenance department is responsible for maintenance and servicing of all equipment.
- All major instruments like HPLC, Analytical balances are calibrated, maintained and serviced by the contract service engineer.
- Records pertaining to calibration and servicing of the instruments are maintained and stored which are available to the user of the instrument.
- Balance verification is done on regular bases internally.

3.9 Qualification, Validation and Calibration :

- Validation is carried out according to Master Validation Plan.
- For equipment installation qualification protocol, Operational qualification protocol and performance qualification protocol are prepared and executed.
- Process validation includes identification of critical parameters and their control variable, responses for control variables are observed and checked whether acceptance criteria have met or not.

- Development batches are not released for sale. Validation batches may be released if they meet all the validation requirements and specifications.

- There is a programme for equipment calibration for which records are kept.

3.10 Sanitation :

Cleaning procedure for manufacturing areas and equipment's.

- There are written standard procedures for cleaning, sanitizing agents and their concentration for the method of cleaning and frequency. Sanitizing agents are used alternatively to avoid development of resistance.
- A matrix has been prepared and products have been grouped accordingly to use of the equipment. Worst case for two combination of product is selected and maximum residual limit is calculated. Cleaning is performed as per standard operating procedure and swab sample is taken & analyzed for the presence of residue of the previous product.
- For monitoring cleaning, environment-monitoring program is prepared. SCDA plates and SDA plates are exposed as per the prescribed frequency and results are monitored. For viable and non – viable particles count, air sampling is done and results are monitored.
- Water systems, air systems and dust extractor systems are cleaned / sanitized according to written procedures.

3.11 Waste Management

- ***Waste water Effluent***

A dedicated water effluent treatment plant is located in the premises.

The wastewater effluent generated during the washing or during the production processes is collected in storage tank. Bacterial and chemical treatment is given to meet the specification. Treated water is analyzed and used for gardening purpose/drainage only.

4 DOCUMENTATION

4.1 Arrangements for Preparation, Revision and Distribution of Documentation :

- Document control is one of the responsibilities of Quality Assurance. All the documents like Batch records, Standard Operating Procedure, Specifications, Standard Testing Procedure, Validation protocols and reports are controlled by document control department

- Preparation and revision of the documents is the responsibility of concerned department. Distribution and control is the responsibility of Quality Assurance Department.

- The Filled Batch Records are kept for a period of five years.

4.2 Other Documents related to Product Quality :

The following documents are developed, prepared and issued in a standard format under the authority of the unit head and the approval of quality assurance:

- Raw material / Packing material / In-Process / Finished Product specifications
- Training modules.
- Process validation Protocols
- Equipment/Instrument calibration records
- Validation Documents.
- Batch Manufacturing Records and Batch Packing Records.

5 PRODUCTION

5.1 Brief description of Production Operations :

- During manufacturing the related batch records are filled concurrent to the activity. The manufacturing of a batch is carried out in strict accordance with Batch Records. Reconciliation is done at all critical stages of manufacturing and at completion of packaging operation.

5.2 Arrangement for handling Starting Materials, Packaging Materials, Bulk and Finished Products including Sampling, Quarantine, Release and Storage :

- Each consignment of material after receipt is visually examined. Different batch materials are segregated. Separate zones are earmarked for “Quarantine / on test”, Approved and rejected status of raw and packing material.
- The damaged or improperly labelled goods are separated as “Rejected” and referred to Quality Control for further instructions for disposal or return.
- Separate areas have been allocated for storage of raw materials, packing materials. Raw materials are stored at controlled temperature depending upon the storage requirement of the material. Packing materials are stored at room temperature.
- Printed packaging materials like labels, cartons, printed foil are stored in an area that is under lock & key, and with restricted entry for authorized personal.

- Standard Operating procedures for sampling of the raw materials and packaging materials are available and followed. Sampling of the raw material is done under reverse laminar air flow bench.

- Semi-finished and finished goods are sampled by QA. Semi-Finished goods are taken for packing after QA release based on the results of intermediate product (if applicable), review of batch record.

- All Packing materials received from stores are verified as per Batch Records and issued to packing lines. In-process checks are carried out during packing Operation.

- Finished Goods are quarantined till release by Quality Assurance.

- The authorized persons ensure that the goods are manufactured, as per the approved Batch Records and SOPs and also to ensure that the in-process and finished product test results are acceptable.
- All key parameters during manufacturing observed. In process checks of all critical parameters are made by both production and Quality Assurance department and is recorded.

5.3 Arrangement for Handling Rejected Material and Products :

All rejected materials are identified by Red coloured “Rejected” labels. The Quality Control persons affix “Rejected” labels.
Quality Assurance decides the fate of such rejected material. The necessary documents are prepared and recorded for the action taken.

5.4 Brief Description of Process Validation Policy :

Process validation is carried out using following 4 approaches.

1. Prospective Validation
2. Concurrent validation
3. Retrospective validation
4. Revalidation

Prospective process validation is carried out for initial 3 consecutive batches. All key parameters of all critical stages are validated and their measured responses are noted down.
Process validation protocol contains :

- Introduction
- Purpose of validation
- Scope of validation
- Responsibility
- Procedure
- Process flow chart
- Sampling plan and procedure
- Conclusion and report.

6 QUALITY CONTROL

6.1 Activities of Quality Control Department :

Activities of Quality Control Laboratory

- Quality Control is independent of Production.
- All the incoming materials are sampled in accordance with a set of sampling plan and are given a unique analytical reference number. For all in active and active raw materials control samples are retained for 5 years and For finished product control sample are retained for one year after expiry date on product pack. Analysis is performed using approved specifications and analytical methods.

- **General activities of quality control :--**
  - ♦ Approval of raw material, finished product and packaging material specifications.
  - ♦ Establish, verify and implement Quality Control procedures.
  - ♦ Correct sampling, testing and approving of raw materials, Packaging components, in-process samples and finished products.
  - ♦ To check and carry out inspection and analysis of control samples.
  - ♦ To maintain control sample of raw material and Finished Product.

Activities of Quality Assurance

- To monitor G.M.P. standards in the plant
- Assist with validation of equipment/process/product
- To review and audit batch documents before release of a batch
- To audit and follow up corrective actions for compliance
- Line clearance in production and packaging
- To carry out process control deviation, analysis and implement corrective action plan
- QA inspector online reviews the batch records and documents and release of bulk, semi-finished product, and finished products, and Finished Product.
- To monitor in-process testing of production and packing processes.
- All the specifications and test methods are prepared / revised by ADL approved by QA - Head. The specifications are updated on a regular basis.

7 DISTRIBUTION, COMPLAINTS AND RECALLS

7.1 Recording system for distribution :

- The approved finished products are transferred and stored in finished product warehouse. The warehouse is secured and well maintained.
- Finished products are stored in A/C stores.
- The materials are stored in slotted-angle racks.
- Finished products are distributed by road or by air.

7.2 Handling of Complaints and product recall:

Complaints

QA and production investigate all market complaints jointly. QA Head reviews the investigation report and replies to the complainant suitably. All market complaint records are maintained till one year beyond the expiry of the product.

Product Recalls

QA head informs the distribution department to initiate the recall of suspected batch from the market. A thorough investigation is carried out. Simultaneously Local FDA is also informed regarding the recall of the batch. All efforts are made to affect the recall below the wholesale level.

Regulatory authorities through country agents of all countries to which product is exported are informed about the recall of the suspected batch. Country agent must take appropriate action as per country's regulations. Decision to recall a product may result in suspension of manufacturing of the product, if required

8 Self - inspection

Self-inspection is done in accordance with written standard operating procedure. Audit is conducted by reviewing the department / sections compliance with the requirements of Good Manufacturing Practice and its performance against documented procedures, records etc. A report of any non-conformance noted during the audit is prepared. A copy of the audit report is sent to the head of each department (HOD) audited. Observations are given to each respective HOD for taking corrective action. Action is followed-up by QA for compliance.