Inspection Report for Pharmaceutical Industry

1. Name and Address of Company :

2. Manufacturing Licence No. :

   2.1 Non-biological :
   2.1.1 Items (included) :
   2.2 Biological :
   2.2.1 Items (included) :

3. Reason for Inspection :

   3.1 Memo No.

4. Member of Inspection Team:

5. Persons given interview with the team (Manager/Technical personnel)

	Name	Designation	Experience
5.1			
5.2			
5.3			
5.4			

6. Premise:

6.1 Total land of firm :
6.2 Area for Building and installations :
6.3 Is there Lay out plan ? : Yes ☐ No ☐

6.4 Building /Semi-building : One storied ☐ Multi-storied ☐

6.5 Construction and painting materials (Put ☐ where appropriate)

6.5.1 Floor : ☐ Cement/ ☐ Mosaic/ ☐ Fabricated/ ☐ Synthetic painted/ ☐ Others

6.5.2 Wall : ☐ Cement/ ☐ Fabricated/ ☐ Synthetic painted/ ☐ Others

6.5.3 Ceiling : ☐ Cement/ ☐ Fabricated/ ☐ Synthetic painted/ ☐ Others

6.6 Description of premises:

7. Personnel:

7.1 Qualified persons involved in production

Name: Designation: Qualification:

7.2 Qualified persons involved in quality control/assurance

Name: Designation: Qualification:

7.3 Total number of persons working in the factory:

7.3.1 Technical 7.3.2 Non-Technical

7.4 Is there separate dress changing and washing facilities?: Yes/No

7.5 Is there regular training on GMP and records retained : Yes/No

7.6 Has anyone joined GMP training organized by DA : Yes/No (if yes)

7.6.1 When and where? :

7.7 Is there a regular health checking for worker and record retained? Yes/No.

8. Utility services (Water, gases, air and electricity supply)[?]

8.1 Water

8.1.1 Source (please tick as appropriate)

- ☐ Supply water
- ☐ Deep tube well
- ☐ Pond/Lake
- ☐ River

8.1.2 Treatment

- ☐ Demineralization
- ☐ Distillation
- ☐ Double distillation
- ☐ Filtration
- ☐ Reversed osmosis
- ☐ Others (specify):

8.1.3 Water: Control (test done)

[?] N/R = Not required

- ☐ Routine analysis
- ☐ Conductivity
- ☐ Microbial test
- ☐ LAL/Endotoxin

8.2 Gases available and used

- ☐ Natural
- ☐ Oxygen
- ☐ Acetylene
- ☐ Ethylene oxide
- ☐ Nitrogen
- ☐ Helium
- ☐ Carbon dioxide
- ☐ Others (specify):

8.2.1 Precaution Taken:

8.3 Electricity (Power): Source (e.g. PDB, REB etc.)

8.4 Air (HVAC System)

- ☐ Air condition
- ☐ Vacuum/Compressed air
- ☐ Dehumidifier
- ☐ Air Filtration

9. Raw and Packaging Material Storage

9.1 Raw materials: Separate room/area for;

9.1.1 Quarantine: Yes ☐ No ☐

9.1.2 Weighing Yes ☐ No ☐

9.1.3 Sampling Yes ☐ No ☐

9.1.4 Cool store: Yes ☐ No ☐

9.1.5 Cold store Yes ☐ No ☐

9.1.6 Narcotic Yes ☐ No ☐

9.1.7 Flammable & hazardous substances Yes ☐ No ☐

9.2 Is there a sampling plan? Yes ☐ No ☐

9.3 Record of material maintained by:

Register ☐ Bin Card ☐ Data-based ☐ None ☐

9.4 Status label for raw material (e.g. color coded) Yes ☐ No ☐

9.5 Retest plan for raw materials (stored for long time) Yes ☐ No ☐

10. Safety and Hygiene

10.1 Type of fire extinguisher available

- ☐ 10.1.1 Water
- ☐ 10.1.2 Foam
- ☐ 10.1.3 Fire blanket
- ☐ 10.1.4 Carbon dioxide
- ☐ 10.1.5 Others:

10.2 Is there any alternate fire exit? Yes ☐ No ☐

10.3 Is there a first aid facility? Yes ☐ No ☐

10.4 Is there a person for safety aspect? Yes ☐ No ☐

10.5 Is there an accident book to record accident? Yes ☐ No ☐

10.6 Is there a laboratory Safety manual? Yes ☐ No ☐

10.6.1 Is the safety procedure followed? Yes ☐ No ☐

10.7 Is there a written cleaning and sanitation program? Yes ☐ No ☐

10.8 Cleaning agent and disinfectant used:

- 10.8.1 Cetrimide ☐
- 10.8.2 IPA/Ethanol ☐
- 10.8.3 Formaldehyde ☐
- 10.8.4 Benzalkonium Chloride ☐
- 10.8.5 Chorohexidine ☐
- 10.8.6 Sodium Hypochloride ☐
- 10.8.7 UV Light ☐
- 10.8.8 Others (specify): ☐

10.8 Is the monitoring system for microbial count? Yes ☐ No ☐

10.9 Is there a cleaning status label on equipment? Yes ☐ No ☐

11. Manufacturing and Processing Area

11.1 Is there a separated room/area for special product? Yes ☐ No ☐

11.2 Is the weighing room in this area? Yes ☐ No ☐

11.2.1 Is there dust extraction facilities? Yes ☐ No ☐

11.3 Type of dosage form manufactured

- ☐ 11.3.1 Oral liquid (Fill Appendix 1)
- ☐ 11.3.2 Dry syrup (Fill Appendix 2)

☐ 11.3.3 Tablet (non-coated and coated, Fill Appendix 3)

☐ 11.3.4 Capsule-Hard shell gelatin/vegetable/soft shell (Fill Appendix_4)

☐ 11.3.5 Injection (Fill Appendix_5

☐ 11.3.6 Semisolid: Ointment/Cream (Fill Appendix_6)

☐ 11.3.7 Aerosol (Fill Appendix_7)

☐ 11.3.8 Raw materials (Fill Appendix_8)

☐ 11.3.9 Medical Device (Fill Appendix_9)

12. Quality Control

12.1 Is there a separate area/room for (Please tick or cross as appropriate):

a. Sensitive Instruments ☐

b. Chemical laboratory ☐

c. Microbiological test method ☐

d. Biological test method ☐

e. Radioisotope test method ☐

f. Animal house ☐

g. Storage space for samples, reference standards and records ☐

12.2 Is there a separate air handling unit:

a. Fume hood/Fume cupboard ☐

b. AC/dehumidifier ☐

12.3 Chemical and Instrument Laboratory: Facilities available

12.3.1 Analytical balance ☐

12.3.2 PH meter ☐

12.3.3 Conductivity meter ☐

12.3.4 Viscometer ☐

12.3.5	Refractometer	☐
12.3.6	Polarimeter	☐
12.3.7	IR moisture balance	☐
12.3.8	KF titrator	☐
12.3.9	IR Spectrophotometer	☐
12.3.10	UV Spectrophotometer	☐
12.3.11	HPLC	☐
12.3.12	GLC	☐
12.3.13	Electrolyte analyzer	☐
12.3.14	Titrator (Potentiometric/Argentometric)	☐
12.3.15	Atomic absorption spectrophotometer	☐
12.3.16	Flourescence Spectrophotometer	☐
12.3.17	Particle counter	☐
12.3.18	Air particulate matter counter	☐
12.3.19	DOP test apparatus	☐
12.3.20	Flame photometer	☐
12.3.21	Osmometer	☐
12.3.22	Dissolution test apparatus	☐
12.3.23	Disintegration test apparatus	☐
12.3.24	Friability test apparatus	☐
12.3.25	Harness test apparatus	☐
12.3.26	Leak test facilities	☐
12.3.27	Melting point apparatus	☐
12.3.28	Muffle furnace	☐
12.3.29	Hot air oven	☐

12.3.30	Hot water-bath	☐
12.3.31	Ultrasonic bath	☐
12.3.32	Hot plate	☐
12.3.33	Magnetic stirrer	☐
12.3.34	Vacuum evaporator	☐
12.3.35	Vacuum pump/flask	☐
12.3.36	TLC	☐
12.3.37	Thermocouple/Pyrometer	☐
12.3.38	Reference standard	☐
12.3.39	Climate Chamber	☐

12.4	**Biological and Microbiological Laboratory**: Facilities	
12.4.1	Separate room with air-lock entrance	☐
12.4.2	Temperature controlled	☐
12.4.3	Laminar air flow unit	☐
12.4.4	Sterility test facilities	☐
12.4.5	Microbial test facilities	☐
12.4.6	LAL/Endotoxin test kits	☐
12.4.7	Dry heat sterilizer	☐
12.4.8	Autoclave	☐
12.4.9	Incubator	☐
12.4.10	Refrigerator	☐
12.4.11	Colony counter	☐
12.4.12	Air sampler	☐

12.4.13	Microscope	☐
12.4.14	Zone counter	☐

12.5. Tests performed (should be supported by data, table, graph, calculation etc.)

12.5.1	Chemical tests (identification)	☐
12.5.2	Limit test	☐
12.5.3	Related substances	☐
12.5.4	Moisture content:	
12.5.4.1	LOD	☐
12.5.4.2	KF	☐
12.5.5	Bulk density	☐
12.5.6	Weight variation	☐
12.5.7	Volume	☐
12.5.8	Disintegration	☐
12.5.9	Dissolution	☐
12.5.10	Density (wt/ml)	☐
12.5.11	Refractive index	☐
12.5.12	Optical rotation	☐
12.5.13	**Assay**	
12.5.13.1	Spectrophotometric	☐
12.5.13.2	Chromatographic	☐
12.5.13.3	Titration	☐
12.5.13.4	Potentiometric	☐
12.5.13.5	Polarographic	☐
12.5.13.6	Amperometric	☐
12.5.13.7	Coulometric	☐

12.5.13.8	Microbial	☐
12.5.14	Pyrogen	☐
12.5.15	LAL/Endotoxin	☐
12.5.16	Bacterial count	☐
12.5.17	Particle size/count	☐
12.5.18	Air particulate matter	☐
12.5.19	Others:	
12.5.20	Statistical analysis	
12.5.20.1	Precision and accuracy	☐
12.5.20.2	Regression	☐
12.5.20.3	T – test	☐
12.5.20.4	F – test	☐
12.5.20.5	Standard error	☐
12.5.21	Stability study (should be supported by kinetic data)	
12.5.21.1	Real time	☐
12.5.21.2	Accelerated	☐
12.5.22	Comments:	

13. Documentation (available)

13.1 Specification and test procedures ☐

13.1.1 Are the test procedure described validated and relevant to available facilities? ☐

13.1.2 Pharmacopoeias, reference standard, reference spectra etc. ☐

13.2 Specification for starting and packaging materials: ☐

13.2.1 Qualitative and quantitative requirement with acceptable limit ☐

13.2.2 Specimen of printed material ☐

13.2.3 Direction for sampling and testing ☐

13.2.4 Storage condition and precaution ☐

13.2.5 Maximum period of storage before re-examination ☐

13.3 Specification for intermediate and bulk products ☐

13.4 Specification for finished products ☐

13.5 Master formulae ☐

13.6 Packaging Instruction ☐

13.7 Batch processing records ☐

13.8 Batch packing records ☐

13.9 Standard operating procedure (SOPs) and records for:

13.9.1 Sampling ☐

13.9.2 Batch numbering procedure ☐

13.9.3 Manufacturing includes:

13.9.3.1 Receipt of raw materials and component ☐

13.9.3.2 Quarantine and storage ☐

13.9.3.3 Quality control system and approval ☐

13.9.3.4 Release and rejection of products ☐

13.9.3.5 Weighing and compounding ☐

13.9.3.6 Processing and production procedure ☐

13.9.3.7 Packaging and labeling ☐

13.9.3.8 In-process quality control ☐

13.9.3.9 Finished products quality control ☐

13.9.3.10 Storage of finished products ☐

13.9.3.11 Distribution ☐

13.9.3.12 Returned goods ☐

13.9.3.13 Recall and complain ☐

13.9.3.14 Cleaning and sanitation ☐

13.9.3.15 Engineering and maintenance ☐

13.9.3.16 Water supply and quality ☐

13.9.3.17 Operating machine and instrument ☐

13.9.3.18 Equipment assembly, validation and calibration ☐

13.9.3.19 Personnel qualification, training, clothing and hygiene ☐

13.9.3.20 Environmental monitoring ☐

13.9.3.21 Pest control ☐

14. Waste disposal

14. Waste disposal system (facilities available)

14.1 Written and authorized procedure for waste disposal ☐

14.2 Effluent treatment plant ☐

14.3 High temperature incinerator ☐

14.4 Others:

15. Proposal and recommendation