

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)

<u>Name</u>	<u>Designation</u>	<u>Experience</u>
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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:

Routine analysis
Conductivity
Microbial test
LAL/Endotoxin

8.2 Gases available and used

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

8.2.1 Precaution Taken:

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

8.4 Air (HVAC System)

Air condition	Dehumidifier
Vacuum/Compressed air	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 Chlorhexidine
- 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 Fluorescence 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 | <input type="checkbox"/> |
| 12.3.31 | Ultrasonic bath | <input type="checkbox"/> |
| 12.3.32 | Hot plate | <input type="checkbox"/> |
| 12.3.33 | Magnetic stirrer | <input type="checkbox"/> |
| 12.3.34 | Vacuum evaporator | <input type="checkbox"/> |
| 12.3.35 | Vacuum pump/flask | <input type="checkbox"/> |
| 12.3.36 | TLC | <input type="checkbox"/> |
| 12.3.37 | Thermocouple/Pyrometer | <input type="checkbox"/> |
| 12.3.38 | Reference standard | <input type="checkbox"/> |
| 12.3.39 | Climate Chamber | <input type="checkbox"/> |

12.4 **Biological and Microbiological Laboratory: Facilities**

- | | | |
|---------|--------------------------------------|--------------------------|
| 12.4.1 | Separate room with air-lock entrance | <input type="checkbox"/> |
| 12.4.2 | Temperature controlled | <input type="checkbox"/> |
| 12.4.3 | Laminar air flow unit | <input type="checkbox"/> |
| 12.4.4 | Sterility test facilities | <input type="checkbox"/> |
| 12.4.5 | Microbial test facilities | <input type="checkbox"/> |
| 12.4.6 | LAL/Endotoxin test kits | <input type="checkbox"/> |
| 12.4.7 | Dry heat sterilizer | <input type="checkbox"/> |
| 12.4.8 | Autoclave | <input type="checkbox"/> |
| 12.4.9 | Incubator | <input type="checkbox"/> |
| 12.4.10 | Refrigerator | <input type="checkbox"/> |
| 12.4.11 | Colony counter | <input type="checkbox"/> |
| 12.4.12 | Air sampler | <input type="checkbox"/> |

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