FACILITY QUALIFICATION PROTOCOL CUM REPORT

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REVISION HISTORY

Rev.	Date	Authorized By:	Revision Summary
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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FACILITY QUALIFICATION PROTOCOL CUM REPORT

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FACILITY QUALIFICATION PROTOCOL CUM REPORT

1.0 Protocol Approval Sheet:

Prepared By (Name & Designation)	Signature	Date
(Maintenance)		
(Quality Assurance)		

Checked By (Name & Designation)	Signature	Date
(Production)		
(Maintenance)		
(Quality Control)		
(Quality Assurance)		

Approve By (Name & Designation)	Signature	Date
(Quality Assurance)		

FACILITY QUALIFICATION PROTOCOL CUM REPORT

2.0 Objective: The objective of facility design qualification is to ensure that the critical aspects of GMP's, Product/process requirements, safety, environment, statutory requirements and environment.

3.0 Scope: This facility design qualification protocol cum Report is applicable for facility.

4.0 Responsibility:

4.1 Maintenanceshall be responsible for

4.1.1 Preparation, check, Execution, compilation, and review of data.

4.2 Production shall be responsible for:

4.2.1 Check and Execution of the Protocol cum Report.

4.3 Quality Control shall be responsible for:

4.3.1 Check and Execution of the Protocol cum Report.

4.4 Quality Assurance shall be responsible for:

4.4.1 Check, Execution and Approval of Protocol cum Report.

5.0 Facility Design BriefDescription:First floor: Change rooms, Passage area, Granulation area, Blending area, Compression area, RM day store, Bulk day store, Capsule filling area, Capsule & Tablets day store, coating area, Dry syrup filling sealing area, strip area, blister area, Autoclave area, injection filling and sealing area, packing hall area.

Second Floor: Administration area, and Air handling area, dispensing & sampling area.

Third Floor: Quality assurance, Quality control and Conference.

6.0 Critical Attributes to be met while designing facility:

6.1 Layout and Designing:

6.1.1 Layout and design must aim to minimize the risk of errors and permit effective cleaning.

6.1.2 Layout and design must aim to easy maintenance in order to avoid cross contamination

6.1.3 Layout and design must aim to minimize the buildup of dust or dirt and in general any adverse effect on the quality of products

6.2 Location and Surroundings:

All measures to be considered in order to avoid risk of contamination from external environment which includes open sewage, drain, public lavatory or any factory which produces disagreeable or obnoxious odor, fumes, excessive soot, dust, smoke, or chemical emissions.

6.3 Premises:

Premises shall be designed & equipped so as to afford maximum protection against the entry of rodents, crawling insects, flying insects, lizards, flies, birds & other animals.

6.3.1 The premises shall be provided with adequate working space to allow orderly & logical placement of equipment's.

6.3.2 Movement of materials and personnel shall be considered while designing the facility so as to avoid any risk of mix-up, avoid possibilities of contamination, cross contamination & crisscross movements.

6.3.3 Lighting shall be given due importance in all areas within & outside the facility so as to carryout various operations with ease & comfort.

6.3.4 Drain pits shall be designed to prevent back flow, wherever drainage is provided, the same shall be concealed.

6.3.5 Air handling systems shall be designated to provide class 100,000 at rest in areas where product is directly exposed to environment. Air handling systems shall be dedicated to avoid possibilities of cross contamination.

6.3.6 Wood shall not be used anywhere in the production and storing area.

6.3.7 Adequate areas shall be designated to allow sufficient and orderly warehousing of various categories of materials and products like starting (raw materials) and finished products.

6.3.8 Temperature & related humidity controls shall be provided for processing of capsule formulations.

6.3.9 Various areas in the stores shall be clearly segregated. Any system replacing physical quarantine shall give equivalent assurance of segregation.

6.3.10 Separate, safe & secured area shall be provided for printed packaging materials.

6.3.11 Dispensing area(s) with class 100,000 environments.

6.3.12 Production areas shall be designed to allow the production in uni-flow with logical sequence of operations.

6.3.13 Working & in process space shall be adequate to permit orderly & logical positioning of equipment's& man-material movements.

6.3.14 Electrical fittings, pipe work, ventilation openings & service lines shall be designed, fixed and constructed to avoid creation of recesses. They shall be concealed. Service lines shall be identified by colors & the nature of supply & the direction of flow shall be marked /indicated.

6.3.15 Primary & Secondary change rooms for gowning /degowning shall be provided.

6.3.16 Toilets shall not be directly connected with production or storage areas.

6.3.17 Analytical development laboratory shall be independent from the production areas. Separate areas shall be provided each for physico-chemical materials testing.

6.3.18 Stainless steel furniture shall be provided in Analytical development laboratory.

6.3.19 Sufficient & suitable storage space shall be provided for test samples, retained samples, reference standards, records etc.

6.3.20 Laboratory shall be provided with potable water & purified water for cleaning and analysis purposes.

6.3.21 Lighting in each area of the facility shall be adequate enough to perform activities with ease and comfort.

6.3.22 Lighting fixtures shall be of clean room type.

6.3.23 Dust extraction system to be considered in process area where generation of powder dust is expected during processing.

6.4 Floor:

6.4.1 The floor shall be hard, smooth, non-porous, washable, continuous, chip resistant and durable. There shall be no crevices, cracks or open joints in the floor, epoxy floor shall be considered in areas where product is exposed.

6.4.2 Floor to wall joint shall be coved.

6.4.3 Material used for flooring shall permit easy cleaning and shall not shred any particulate matter.

6.5 Walls:

6.5.1 The external walls shall be cement plastered, made with table-molded bricks.

6.5.2 The internal partition walls shall be made with aluminum panel with smooth finish, anti-static, anti-fungal and avoid flaking.

6.5.3 Internal corner of the walls coved with aluminum and silicon.

6.6 Ceiling:

6.6.1 The ceiling shall be hard, non porous, smooth, cleanable and chip resistant.

6.6.2 The wall to ceiling joints shall be coved.

6.7 Doors and View Panels:

6.7.1 The doors shall be non-porous, smooth, cleanable and flushed with its view panel.

6.7.2 Double glass sealed view panels.

6.7.3 Doors shall open on the same side of the airflow.

6.8 Utilities to be Provided:

6.8.1 1 Air handling units (Re-circulatory, once through and ventilation).

6.8.2 Purified water and Water for Injection with distribution network in the form of loop.

6.8.3 Compressed air system with distribution network.

6.8.4 Effluent treatment plant.

6.8.5 Power generator backup.

6.9 Electrical Requirements:

6.9.1 Single phase & three phase electrical points shall be provided in the facility as per design requirements.

6.9.2 Critical areas and critical equipments shall have back up system in the event of power failure.

6.9.3 Earthling shall be provided to all the points.

6.9.4 Electric wiring shall be concealed.

6.9.5 Flame proof wherever required to be provided.

6.9.6 The lighting units are scientifically apportioned so as to provide adequate light for the area in which they are used.

6.9.7 Light fixtures shall be accessible to allow proper maintenance, cleaning & to prevent accumulation of dust or foreign matter.

6.10 Safety Aspects:

6.10.1 Smoke detectors.

6.10.2 Fire extinguishers.

6.10.3 Easy access to first aid kit.

6.10.4 Camera system.

6.10.5 Solvent storage complying the local statutory regulations.

6.10.6 Round the clock security for the premises.

6.11 Regulatory Requirements:

6.11.1 Industrial development corporation, Himachal Pradesh.

6.11.2 State electricity board.

6.11.3 State pollution control board.

6.11.4 Factory inspectorate.

6.11.5 Food and drugs administration, Himachal Pradesh.

6.12 Equipment's:

6.12.1 cGMP complied process equipment's are provided to prevent cross contamination

7.0 Observation (Section wise):

The facility shall be monitored to verify the architectural particular, HVAC particulars, Power and Electrical particulars, purified water particulars, Identification of Instruments Requiring Calibration, Identification of Needs of SOP, Drawings particulars and Other Utilities Particulars for the following areas. Refer;

Annexure – I (Granulation Area)

Annexure – II (Blending-II area)

Annexure – III (Dirty Equipment Wash area)

Annexure – IV (Clean equipment area)

Annexure – V (RM Day Store area)

Annexure – VI (Blending-I Area)

Annexure – VII (Blend Store Area)

Annexure – VIII (Capsule Filling area)

Annexure – IX (Filled Capsule & Tablets store Area)

Annexure – X (Tablet Compression-I Area)

Annexure – XI (Tablet Compression-II Area)

Annexure – XII (Tablet Coating Area)

Annexure – XIII (Dry Syrup Filling & Sealing Area)

Annexure – XIV (Strip Packing Area)

Annexure – XV (Blister Packing Area-I)

Annexure – XVI (Blister Packing Area-II)

Annexure – XVII (IPQA Area)

Annexure – XVIII (Autoclave loading side)

Annexure – XIX (Autoclave UN loading side)

Annexure – XX (Vial filling room)

Annexure – XXII (Vial sealing room)

Annexure – XXIII (Dispensing/Blending room)

8.0 Specification (Room wise):

Design specifications in minute details shall be finalized for each room/section of the Facility .Design Requirements with respect to following points shall be finalized & enclosed to this protocol.

8.1 Room Dimensions (L x B x H)

8.2 Area in Square feet

8.3 Floor

8.4 Coving

8.5 Walls

8.6 Doors

8.7 View Panels

8.8 Ceiling/false Ceiling

8.9 Electrical fittings, lighting fixtures

8.10 Drain Point

8.11 No of Supply Air/Return

8.12 Machine

8.13 Water system

9.0 Summary and Conclusion

8.1 Summary:

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8.2 Conclusion:

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10.0 Post Approval Sheet:

Executed By (Name & Designation)	Signature	Date
(Maintenance)		
(Production)		
(Quality Control)		
(Quality Assurance)		

Approved By (Name & Designation)	Signature	Date
(Quality Assurance)		