PERFORMANCE

QUALIFICATION PROTOCOL FOR FLUID BED DRYER

EQUIPMENT ID: ……..

LOCATION: GRANULATION AREA (…….BLOCK)

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No	……..

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PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR FLUID BED DRYER

1.0 PROTOCOL APPROVAL :

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To provide documented evidence that the equipment is performing as per the parameter defined in performance qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the equipment will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the equipment.

3.0 SCOPE :

- The Protocol covers all aspects of Performance qualification for the Fluid bed dryer being used at ……..
- This Protocol will define the methods and documentation used to qualify the Fluid bed dryer for PQ.

4.0 RESPONSIBILITY:

The Qualification Team, comprising of a representative from each of the following Departments, shall be responsible for the overall compliance of this Protocol:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Protocol Activity • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol • Analytical Support (Analysis)
Engineering	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.

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5.0 EQUIPMENT DETAILS:

Equipment Name	**FLUIDIZED BED DRYER**
Manufacturer's Name	
Location of Installation	**Granulation Area**
Equipment ID No.	

6.0 SYSTEM DESCRIPTION:

The principle of FBD is to operate a fluidal turbulence in a granulated or powdery wet product by means of hot air flowing in an upward direction and to dry the same to the final required degree.

In fluid bed dryer the wet material is transposed to a fluidized state by hot airstreams that surrounds the material completely & therefore the heat transfer rate achieved is very high & the temperature distribution throughout the product is uniform. Due to this drying time is considerably reduced & therefore high production rates are achieved in comparison to other dryers as the product is in the close contact with hot air at low temperature & also for short duration. The physical & chemical properties of the product are generally not affected & therefore the dryer can affectively be used for the heat sensitive products. Due to movement of product during drying, lump formation, case hardening, etc is minimized. The fluid bed dryers are not suitable for drying of liquids or pasty material.

The equipment shall be qualified against the specification described in User Requirement Specification, Design data sheet used as purchase order specification and the Specification provided by the supplier**.**

Fluid Bed Dryer mainly consists of:

1) **Main Body** : The main body of FBD is a cylindrical retarding chamber & filter bag housing with vertical explosion chamber i.e. shell type slab mounted machine with dish type cylindrical bottom body.

The Accessories fitted on main body are:

a) Sealing Gaskets
b) Glass Window & Covers
c) Product Container Stoppers
d) Earthing Device
e) Pneumatic Shaking Cylinder mounting bar.
f) Blower inlet nozzle

g) Explosion frame & flap

2) **Outlet Shut Off Valve:** It is an isolating valve between main body & air preparation unit. The type of valve is ON/OFF type butter fly valve & a pneumatic actuator operates the flap. This remains close when the equipment is not in use or during bag shaking.

3) **Air Preparation Unit**: It is a rectangular housing to accommodate air filter (10 + 5 + 0.3 microns) the one end is provided with filter mounting frame while other with a transition duct for changing rectangular section to narrow duct.

The Accessories fitted in this unit are:

a) Steam Inlet & Outlet Nozzle
b) Duct Reducer
c) S.S 304 Radiator
d) Air Filter 10 + 5 + 0.3 microns
4) Product Container & Trolley
5) Explosion Frame & Flap
6) Filter Bag Shaking Device
7) Blower Assembly
8) Sealing Gaskets

7.0 REASON FOR REQUALIFICATION:

Scheduled requalification is required as per requalification schedule and shall be performed according to detailed written procedures with the original qualification parameters and limits used as the evaluation criteria. The requalification studies shall be documented in detail and results of studies shall be compared to the original validation results and evaluated to the same extent. If the results are satisfactory, the equipment shall be certified. If the results are not satisfactory the modified system shall require new qualification studies.

8.0 SITE OF STUDY:

Granulation Area.

9.0 FREQUENCY OF REQUALIFICATION:

- Once in two years
- After any major breakdown or after major modification.
- After Change of Location

10.0 TESTS AND CHECKS

Optimization of Drying time & temperature:

The following tests shall be carried out to establish Performance qualification of "Fluidized bed dryer".

- **Objective :**

  To verify the maximum drying time & temperature (Operational) for smooth running & confirmation of the required moisture level in product.

- **Test Requirements:**

  Stop Watch

  Moisture Analyser

  Product batch Size

- **Procedure:**

  1. The test should be carried out Triplicate.

  2. Switch "ON" the machine & Operate as per SOP.

  3. Load the product batch size & in FBD trolley as per capacity load.

  4. Set the drying time & temperature as per requirement in product batch & all the Parameters should be recorded in the performance requalification report.

  5. Run the FBD & collect the sample at different location at different time interval as per Annexure -I.

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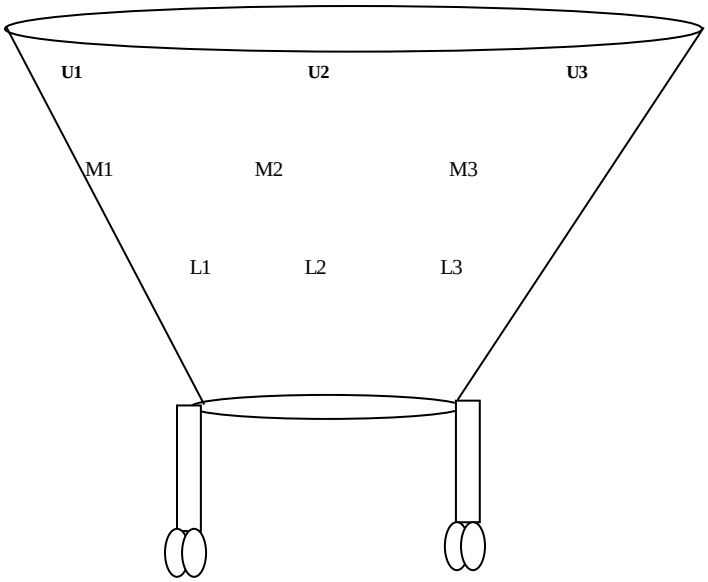
Annexure – I



FBD BOWL

Quantity of Sample: 3.0gm each.

No. of Samples: 3 Sample from top

3 Samples from middle.

3 Samples from lower.

U1 = Upper Left side of FBD.

U2= Upper middle side of FBD.

U3 = Upper right of FBD.

M1 = Middle left of FBD.

M2 = Middle side of FBD.

M3= Middle side of FBD.

L1= Lower left side of FBD.

L2= Lower middle side of FBD.

L3= Lower right side of FBD.

11.0 REFERENCES:

The Principle Reference are the following:

- Validation Master Plan.
- Schedule – M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2.Good Manufacturing Practices and Inspection.

The following references are used to give additional guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.

12.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates
- QC Raw Data

13.0 NON COMPLIANCE:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA shall study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

14.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

All deviations, non conformances and out of specification results obtained shall be investigated in accordance with corresponding SOPs and documented in the requalification report.

15.0 CHANGE CONTROL, IF ANY:

Details of change controls initiated during the re-qualification activity, shall be documented in the requalification report.

16.0 ABBREVIATION:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
PQ	:	Performance Qualification
mm	:	Millimeter
Amp.	:	Ampere
FBP	:	Fluid Bed Processor
GMP	:	Good Manufacturing Practices
SOP	:	Standard Operating Practices
ISPE	:	International Society for Pharmaceutical Engineering