PERFORMANCE QUALIFICATION

PROTOCOL

FOR

FLUID BED DRYER

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PERFORMANCE QUALIFICATION PROTOCOL FOR FLUID BED DRYER

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 (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PERFORMANCE QUALIFICATION PROTOCOL FOR FLUID BED DRYER

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the Fluid Bed Dryer **(Make - Elicon Pharma, Capacity- 300 Kg)** Installed in the …….
- Equipment Transfer from …….
- This Protocol will define the methods and documentation used to qualify the Fluid Bed Dryer for PQ.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Review, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Activity.
Production	• Review of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Performance Qualification Protocol.
Engineering	• Review of Performance Qualification for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Fluid Bed Dryer
Equipment ID.	
Manufacturer's Name	Elicon Pharma
Supplier's Name	Elicon Pharma
Model	GMP Model
Location of Installation	

6.0 SYSTEM DESCRIPTION:

A batch of flow able Moist Material is loaded in the product container. The air is sucked through a blower unit from atmosphere via the pre filter, fine filter and HEPA filter, where it is free from impurities. This clean air is subsequently dehumidified by Dehumidifier heated by steam coil. The clean, dry and heated air moves upward through moist material inside the product container and the product is put in to a fluidized state. By this the entire surface of individual particle gets exposed to the hot air, thus achieving a homogenous distribution of temperature and as a result of this, a rapid and careful drying takes place in minimum time. The air filter bags at outlet prevent product fine particles from escaping, which false back in to the container by operating the pneumatically operated shaking device intermittently during the working process. The outlet air can be regulated by means of the damper with position controller actuator fitted at the outlet and controlled from the control panel. The fan situated on the exhaust side of the Dryer, operates on a negative pressure principle.

INFLATTABLE GASKETS

This Gasket closes hermetically the product container between the retarding chamber and lower plenum during the working process. When operating the control panel gaskets has been brought up to lift the container, the compressed air bifurcates through the pressure regulators and one low goes into the bottom side of inflatable gasket. The time is set in such a way that after lifting the container by inflatable gasket which presses the container with the square shaped rubber gasket, provided between the product container and the groove in retarding chamber.

THE EXHAUST AIR FILTER BAG

The filter bag is mounted by SS quick opening and positive locking type clamps, which are bolted with the filter hanger. The hanger is attached to pneumatic cylinder piston rod by intermediate extension rod. The filter bag can be lifted by pneumatic cylinder through Control panel.

Through Control panel the filter bag locking gasket is inflated with compressed air and the edge of filter bag is sealed off towards the shell so that no product may escape into the outlet air.

THE FILTER BAG SHAKING DEVICE

The automatic shaking device consists of lowering the filter bag at regular intervals by means of a pneumatic pressure cylinder and then lifting it again with a sudden jerk. In this way the filter bags are compressed & then stretched again causing the dust attached to the filters to be shaken off. The required jerky movement is created by opening the rapid ventilator valve called quick exhaust valve (QEV). Throughout the whole shaking process the regulating flap of damper controller remains closed.

7.0 REASON FOR QUALIFICATION:

- Equipment Transfer from ……...
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

…….

9.0 FREQUENCY OF QUALIFICATION:

- Once in two year time period.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE - QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- SOP for Operation & Cleaning of Fluid Bed Dryer.
- SOP for Preventive Maintenance Fluid Bed Dryer.

PERFORMANCE QUALIFICATION PROTOCOL FOR FLUID BED DRYER

11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Fluid Bed Dryer.
- SOP for Preventive Maintenance Fluid Bed Dryer.
- Calibration Status of Measuring Instrument
- Test Product & batch Information

Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

11.2 HEPA Filter Integrity (PAO Test):

11.2.1 Equipments & instruments:

Aerosol photometer and scanning port.

11.2.2 Procedure:

1. Before starting the test start the AHU before one hour.
2. Check PAO (Poly Alfa Olefin) solution level into aerosol photometer tank,
3. Connect the compressed air to aerosol photometer
4. Orient the supply tube (PU tube) of aerosol toward the riser and orient the PU (for Down stream
5. Concentration) tube on opening of supply aerosol tube - than check the upstream Concentration 100 % above the HEPA through port.
6. Keep the aerosol supply tube near the riser grill.
7. Scan the Supply grill (HEPA Grill) for checking filter integrity test. Adjust the concentration of aerosol above HEPA 100%.

11.2.3 Acceptance criteria:

The PAO penetration/leak through HEPA filters should not be greater than 0.01% of the upstream PAO Concentration.

11.3 PERFORMANCE EVALUATION USING PLACEBO FORMULATION:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish the performance based range of operating parameters for performance qualification activity using placebo formulation.

11.3.1 Procedure:

- Record the initial moisture content of the test product.
- Load Placebo formulation in the range of 80 % of capacity to the FBD Bowl.
- Perform Drying at optimized parameters.
- Check all the parameters such as product load, air drying time, inlet air temperature, inlet air RH, outlet air temperature, outlet air RH, raking frequency, raking time, drying time, moisture content against the set values.
- Check all the In-process parameters such as fluidization of material bed, changes in drying parameters according to input, sealing of all components of FBD during operation, lifting up and lifting down function of FBD bowl, functioning of interlocking features during operation against the specified acceptance criteria.
- Continue drying till to achieve the Moisture content /LOD of 2.5-3.5% w/w.
- Collect samples of dried granules from 9 different locations after completion of drying process.
- Analyze collected samples for moisture content.
- Record the observations of drying process parameters and observed moisture content.

11.3.2 Acceptance Criteria:

- Fluidization of material bed should be performed effectively by FBD.
- Alteration of process parameters should occur as per the input values of different drying parameters.
- During operation all components of FBD should be fixed tightly so as to avoid leakage of air from any site.
- FBD bowl should be lifted up and down as per the requirement.
- All interlocking and safety features including alarms should be operating properly during operation.
- Sample collected from different locations should have uniform result for moisture content.

- Moisture content / LOD of 2.5-3.5% w/w should be achieved by drying.
- RSD for moisture content results of all locations should not be more than 5%.
- Integrity of FBD bag and FBD bowl's sieve should be intact.

11.4 PERFORMANCE EVALUATION USING DRUG PRODUCTS:

- To verify the performance of Fluid Bed Dryer in the established operating range.
- To establish documented evidence that the Fluid Bed Dryer is performing consistently and the result of all test parameters meet the pre - defined acceptance criteria of coated products.

Test: Evaluation of Drying Efficiency:

The test is based on drying of the drug products in FBD at established drying parameters and then analyzing the collected samples from different locations of FBD bowl for the moisture content.

11.4.1 Procedure:

- Record the initial moisture content of the test product.
- Load drug product in the range of 80 % of capacity to the FBD Bowl.
- Perform drying at drying parameters as specified in the BMR of product.
- Perform Drying at optimized parameters.
- Check all the parameters such as product load, air drying time, inlet air temperature, inlet air RH, outlet air temperature, outlet air RH, raking frequency, raking time, drying time, moisture content against the set values.
- Check all the In-process parameters such as fluidization of material bed, changes in drying parameters according to input, sealing of all components of FBD during operation, lifting up and lifting down function of FBD bowl, functioning of interlocking features during operation against the specified acceptance criteria.
- Continue drying till to achieve the Moisture content / LOD of 2.5-3.5 % w/w or as per product requirement.
- Collect samples of dried granules from 9 different locations after completion of drying process.
- Analyze collected samples for moisture content.
- Record the observations of drying process parameters and observed moisture content.

11.4.2 Acceptance Criteria:

- Fluidization of material bed should be performed effectively by FBD.
- Alteration of process parameters should occur as per the input values of different drying parameters.
- During operation all components of FBD should be fixed tightly so as to avoid leakage of air from any site.
- FBD bowl should be lifted up and down as per the requirement.
- All interlocking and safety features including alarms should be operating properly during operation.
- Sample collected from different locations should have uniform result for moisture content.
- Moisture content /LOD of 2.5-3.5 % w/w (or As per Product Requirement) should be achieved by drying.
- RSD for moisture content results of all locations should not be more than 5%.
- Integrity of FBD bag and FBD bowl's sieve should be intact.

11.4.3 Sampling Plan:

No. of Samples: 09

Sample Quantity: Approx. 5.0 gm from each sampling location.

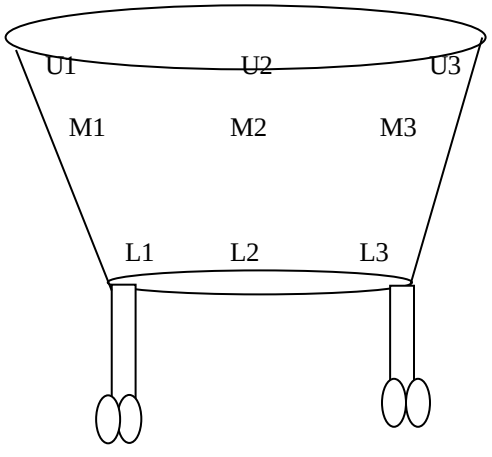
Sampling Locations:

3 Samples from Upper layer (U1, U2 & U3)

3 Samples from Middle layer (M1, M2 & M3)

3 Samples from Lower layer (L1, L2 & L3)

11.4.4 Sampling Locations:



FBD BOWL

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of HEPA Filter Integrity by PAO Test.
- Verification of performance using placebo formulation.
- Verification of performance using drug product.

13.0 REFERENCES:

The Principle References are as 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant document.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- 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 will 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.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

DQ	:	Design Qualification
FBD	:	Fluid Bed Dryer
GB	:	General Block
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	Kilogram
NLT	:	Not Less Than
No.	:	Number
OQ	:	Operational Qualification
PAO	:	Poly alpha Olefin
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
SS	:	Stainless Steel
WHO	:	World Health Organization