OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

FLUID BED DRYER

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

PROTOCOL CONTENTS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

1.0 PROTOCOL PRE-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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Fluid Bed Dryer and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Fluid Bed Dryer (Make- Elicon Pharma, Capacity: 300Kg)** installed in the ……..
- Equipment Transfer from …….
- This Protocol will define the methods and documentation used to perform OQ activity the Fluid Bed Dryer for OQ.
- Successful completion of this Protocol will verify that Fluid Bed Dryer meet all acceptance criteria and ready for Performance Qualification.

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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and compilation of the operational Qualification protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Operational Qualification Protocol Cum Report after Execution
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol Cum Report after Execution.
Engineering	• Review of Operational Qualification Protocol Cum Report. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Operational Qualification Protocol Cum Report after Execution.

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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	cGMP 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.

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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 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of FBD
- SOP for Preventive Maintenance of FBD.

7.1.1 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. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum report.

7.1.2 Acceptance Criteria:

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

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	DOCUMENT / SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY (QUALITY ASSURANCE) SIGN/DATE
1.	**DQ Protocol cum Report**				
2.	**IQ Protocol cum Report**				
3.	**SOP for Operation & Cleaning of Fluid bed dryer.**				
4.	**SOP for Preventive Maintenance of Fluid bed dryer.**				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date:……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

EQUIPMENT / INSTRUMENTS NAME	EQUIPMENT/INSTRUMENT I.D.	CALIBRATION ON	DUE ON	OBSERVED BY SIGN/DATE

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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8.3 Operational And Functional Checks:

Operate the Fluid Bed Dryer as per Manufacturer's Manual/SOP and Check for the following functions of the equipment. The equipment should function as desired.

COMPONENT	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Press the emergency stop located on the control panel body.	All Pneumatic supplies shall be de-energized an appropriate alarm shall be displayed.		
With the "emergency stop pressed" check the PLC outputs.	All plc outputs shall be de-energized.		
With the "emergency stop pressed" check all motors.	Motor contactors shall be de-energized.		
With the emergency stop pressed check the condition of the valve solenoid indicators in the pneumatic panel.	All solenoid indicators shall be extinguished		
On the console with the emergency stop pressed. Reset the emergency stop switch check the condition of the PLC outputs.	The PLC outputs shall remain de-energized		

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COMPONENT	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
On the console acknowledge any alarm and press the system release switch, located by the data panel. Check the condition of the PLC outputs.	The PLC outputs shall be energized.		
Take the finger bag holding in up position.	Finger bag reach up to the proper height.		
Put the bowl in position.	Bowl should be in proper position. Facing the expansion chamber as well as bottom plenum.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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8.4 Data Entry Limit Checking:

COMPONENT	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Take the finger bag holding in up position	Finger bag reach up to the proper height.		
Put the bowl in position	Bowl should be in proper position. Facing the expansion chamber as well as bottom plenum.		
Lift the bowl	Bowl should be lifted properly and titan with the square rubber gasket.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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8.5 Electro Pneumatic Connection Through PLC System:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
From the MMI panel seal the finger bag gasket	The gasket should be seal properly thought out periphery of FBD shell.		
Start the exhaust blower	Exhaust blower should be started.		
Open exhaust damper	Exhaust damper should be opened, magnehalic deflection shall be noted.		
Increase the opening exhaust damper by means of regulator	Exhaust damper should be opened mode can be checked from the magnehalic deflection.		
Close the exhaust damper by means of regulator	Magnehalic deflection should be nearly 0 position.		
Keep the exhaust damper position in half way	It should be in halfway position, can be verify from the magnehalic deflection.		
Start Bag shaking operation	Bag shaking started following the timing set in the MMI/PLC.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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8.6 To Check Temperature Control:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Open the steam valve manually and check the pressure in the pressure gauge	The pressure should be 2-4 bar.		
Set Inlet temperature 50ºC to 80ºC	To be recorded		
Set Outlet temperature 35ºC to 45ºC	To be recorded		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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8.7 Checking Of Auto Mode Operation:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make The Machine In Auto Mode Through MMI	Machine should response in auto mode viewed in MMI.		
Set the parameters like inlet temperature, exhaust temp, bed temperature, process time, bag shaking interval in the set parameter screen and save it with a particular recipe name	PLC should accept the set parameters.		
Load the same recipe to the PLC.	The recipes is loaded.		
Go to main screen and press auto start.	Machine should start automatically following the sequence and as per the set parameters to PLC.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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8.8 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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8.9 Emergency Operation Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop.		
	Equipment should Start.		
With the Emergency Stop Pressed in, in Try to cause movement of an Operating function.	The Equipment will be inoperative.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 REFERENCES:

The Principle Reference is 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

AISI	:	American Iron & Steel Institute
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
FBD	:	Fluid Bed Dryer
HP	:	Horse Power
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	Kilo Gram
KW	:	Kilo Watt
Ltrs	:	Liters
MCB	:	Miniature Circuit Break
mm	:	Millimetre
NLT	:	Not Less Than
No.	:	Number
OQ	:	Operational Qualification
SS	:	Stainless Steel
WHO	:	World Health Organization

17.0 PROTOCOL POST 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)			