INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

FLUID BED DRYER

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

PROTOCOL CONTENTS

INSTALLATION 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)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Fluid Bed Dryer for ……
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Fluid Bed Dryer (Make: Elicon Pharma, Capacity: 300 Kg)** to be installed in the ……..
- Equipment Transfer from …….
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Fluid Bed Dryer.

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 Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in FBD Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol cum Report after Execution.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

5.0 EQUIPMENT DETAILS:

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

6.0 SYSTEM DESCRIPTION:

THE UNIT

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

7.0 PRE- QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- GA Drawing.
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

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 IQ Protocol cum report.

7.1.2 Acceptance Criteria:

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly grind without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Granulation - 08		
Room Condition	Temp NMT 25 ^{o}C		
Illumination	NLT 300 Lux		
Working space around the Equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

……

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

8.2 Technical Specification Checks:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	Fluid Bed Dryer		
S.No.	EP/300 cGMP Model		
Capacity	300 Kg		
Motor			
Make	Crompton Greves		
Type	SCR		
HP	30 HP		
RPM	2920 RPM		
Volt	415V ±10%		
Amp	32 Delta		
Sr.No.	ANH0575		
Pneumatic cylinder for Lifting			
Make	Dancal		
Type	Double Acting (150 NB x 75)		
Quantity			
Pneumatic cylinder for Shaking			
Make	Dancal		
Type	Double Acting (65 NB x 300)		
Quantity			
Filter bag			
Make	N.K. Filter		
Type	Polypropylene		
Pore Sise	10 Micron		
Actuator			
Make	Rotex		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Type	Rotary		
Pre Filter			
Make	‘’Netfil’’		
Type			
Pore Sise	5 Micron		
Size (Inch)	24 x 24 x12 with Flange		
Control Panel			
MOC	SS304		
Temp Controller	Make : ‘’L’’ & ‘’T’’		
Temp Indicator			
Digital process Timer	Make : Radix		
Capacity	Make : Radix		
Earthing Relay	Make : Jayron		
Blower on/off Push Button	Make : “ Technic’’		
Bowl Lifting Selector Switch	Make : “ Technic’’		
Pneumatic cylinder for Lifting			
Make	Dancal		
Type	Double Acting (150 NB x 75)		
Quantity	2Nos		
Pneumatic cylinder for Shaking			
Make	Dancal		
Type	Double Acting (65 NB x 300)		
Quantity	1Nos		
Filter bag			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	N.K. Filter		
Type	Polypropylene		
Pore Sise	10 Micron		
Actuator			
Make	Rotex		
Type	Rotary		
Pre Filter			
Make	‘’Netfil’’		
Type	Flange Type		
Pore Sise	5 Micron		
Size (Inch)	24 x 24 x12 with Flange		
Control Panel			
MOC	SS304		
Temp Controller	Make : ‘’L’’ & ‘’T’’		
Temp Indicator	Make : Radix		
Digital process Timer	Make : Radix		
Capacity	Make : Radix		
Earthing Relay	Make : Jayron		
Blower on/off Push Button	Make : “ Technic’’		
Bowl Lifting Selector Switch	Make : “ Technic’’		
Damper on/off Selector Switch	Make : “ Technic’’		
Manual Shaking Switch	Make : “ Technic’’		
Steam & Earthing Indicating lamp	Make : “ Technic’’		
Model	PT-100 Head Type Sensor		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
PU Wheels (8")	08 Nos.		
Make	Tex Mech Engineers		
Make	Bright Flow Technologies Pvt.Ltd.		
Model	BFA-8		
Sr.No.	K-131487		
CFM	8000		
Static Pressure	65 MM WG		
Motor KW/HP	5.5/7.5		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

……

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

8.3 MOC Verification List:

S.No.	COMPONENT	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
CONTACT PARTS				
1.	**Product Container**	AISI 316 L		
2.	**Retention Chamber**	AISI 316 L		
3.	**Duct Mesh Screen**	AISI 316 L		
4.	**Perforated Plate**	AISI 316 L		
5.	**Sampling Device**	AISI 316 L		
NON-CONTACT PARTS				
6.	**Inlet AHU**	MS Powder Coated/ AISI 304/ Pre Coated (Outer Skin)		
7.	**Damper**	AISI 304		
8.	**WIP Spray Nozzles**	AISI 304 (Optional)		
9.	**Operating Panel**	AISI 304		
10.	**Explosion Chamber**	AISI 304		
11.	**Explosion Flap**	Aluminum		
12.	**Supporting Leg**	AISI 304		
13.	**Power Panel**	MS Powder Coated		
14.	**Heating Coils with Fins**	Copper Tube with Aluminum		
15.	**Cooling Coil**	Copper Tube with Aluminum		
16.	**Ducting Interlocking**	AISI 304		
17.	**Blower Impeller**	MS Powder Coated		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

8.4 Utility Verification List:

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Electricity	Voltage: 415V Phases: 3 Phase Frequency: 50 Hz		
Compressed Air	Pressure: 6 Bar		
	Flow Rate: 8-10 CFM		
Steam Consumption	120-150 Kg /hr Pressure: @ 2-4 Kg / cm^2		
AC Inverter Drive	Shall be properly connected and identified.		
Light Indication for Machine working condition	Shall be properly connected and identified.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

……

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER

8.5 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Joints	Welding of joints without any welding burrs		
Metal Parts	All the metal parts should be Properly grounded without any sharp Edges.		
Leveling & Balancing	Equipment should be properly balanced & leveled.		
Earth safety relay	If improper earthing halts the process		
Emergency Switch	Should be provided at approachable distance		
Motor overload relay	If overload the switchgear trip.		
Temp. sensor air Inlet	If inlet temp. Increases than set value, the steam control valve closes.		
Explosion flap	If released relieves the excess pressure developed during explosion.		
Air Pressure	If Air Pressure lower than required, than stops the process.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

……

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

9.0 REFERENCES:

The Principle References 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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:

……

……

……

……

……

……

……

……

……

12.0 CHANGE CONTROL , IF ANY:

……

……

……

……

……

……

……

……

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

……

……

……

……

……

……

……

……

……

14.0 CONCLUSION:

……

……

……

……

……

……

……

……

15.0 RECOMMENDATION:

……

……

……

……

……

……

……

……

……

……

……

16.0 ABBREVIATIONS:

AC	:	Alternating Current
AISI	:	American Iron & Steel Institute
Amps	:	Amperes
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
FBD	:	Fluid Bed Dryer
HEPA	:	High Efficiency Particulate Air
ID	:	Identification Number
Id	:	Inner Diameter
IQ	:	Installation Qualification
MCB	:	Miniature circuit breaker
MMI	:	Man Machine Interface
MOC	:	Material of Construction
NLT	:	Not Less Than
NMT	:	Not More Than
P & ID	:	Piping & Instrumentation Diagram
PLC	:	Programmable Logic Controller
PQ	:	Performance Qualification
RH	:	Relative humidity
SOP	:	Standard Operating Procedure
Sr	:	Senior
SS	:	Stain less 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)			