



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
FLUID BED DRYER**

<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

**PROTOCOL CONTENTS**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
1.0	Protocol Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Project Requirements	6
6.0	Brief Equipment Description	6
7.0	Equipment Specification	7
8.0	Critical Variables to be Met	7
8.1	Equipment Parameters	7
8.2	Utility Requirement / Location Suitability	8
8.3	Technical Specification /Key Design Features	8-10
8.4	Material of Construction	10
8.5	Safety	11-12
8.6	Vendor Selection	12
9.0	Documents to be Attached	12
10.0	Review (Inclusive of Follow Up Action, If Any)	13
11.0	Any Changes Made Against the Formally Agreed Parameters	13
12.0	Recommendation	13
13.0	Abbreviations	14
14.0	Reviewed By	15



**DESIGN 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)			



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

**2.0 OBJECTIVE:**

- To prepare the Design Qualification document on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification of **Fluid Bed Dryer (Make: Elicon Pharma, Capacity: 300 Kg)** for .....
- Equipment Transfer from .....
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR 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
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review and Approval of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification Activity.</li><li>• Review of Design Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Design Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Review of Design Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Design Qualification Protocol cum Report.</li><li>• Assist in the Preparation of the Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none"><li>➤ GA Drawing.</li><li>➤ Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.</li><li>➤ Details of utilities.</li><li>➤ Identification of components for calibration.</li><li>➤ Material of construction of all components.</li><li>➤ Brief Process Description.</li><li>➤ Safety Features and Alarms.</li></ul></li><li>• Review of Design Qualification Protocol cum Report after Execution.</li></ul>



## **DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

### **5.0 PROJECT REQUIREMENTS:**

To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

### **6.0 BRIEF EQUIPMENT 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.

#### **INFLATABLE 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.



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

**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 EQUIPMENT SPECIFICATION:**

Equipment Specifications are based on User Requirement Specification prepared ..... The manufacturer of equipment ensures complies with User Requirement Specification.

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 EQUIPMENT PARAMETERS:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Application:</b> The FBD should be able to dry the wet granulated mass or powdery wet product to the final required degree.	FBD should meet the requirement for drying of materials for manufacturing of Oral Solid Dosage Form.	Process Requirement
<b>Working:</b> Working of FBD	The FBD should be able to perform drying, Wet granulated mass or powdery wet product to the final required degree.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

**8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Electrical Supply</b>	Power for Electric Drive: Power: 40 HP Voltage: 415 V, 3 Phase ,50 Hz	GMP Requirement
<b>Room Condition</b>	Temperature and RH required as per requirement of product.	Process Requirement
<b>Steam Consumption</b>	120 – 150 Kg/hr @ 2 - 4 Kg/cm <sup>2</sup>	Process Requirement
<b>Compressed Air</b>	8-10 Kg/cm <sup>2</sup> Pressure	Process Requirement

**8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Equipment	Fluid Bed Dryer	Design Requirement
S.No.	EP/300 cGMP Model	Design Requirement
Capacity	300 Kg	Process Requirement
<b>Motor</b>		
Make	Crompton Greves	Design Requirement
Type	SCR	Design Requirement
HP	30 HP	Design Requirement
RPM	2920 RPM	Design Requirement
Volt	415V ±10%	Design Requirement
Amp	32 Delta	Design Requirement
Sr.No.	ANH0575	Design Requirement
<b>Pneumatic cylinder for Lifting</b>		
Make	Dancal	Design Requirement
Type	Double Acting (150 NB x 75)	Design Requirement
Quantity	2Nos	Design Requirement
<b>Pneumatic cylinder for Shaking</b>		
Make	Dancal	Design Requirement





**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Type	Double Acting (65 NB x 300)	Design Requirement
Quantity	1Nos	Design Requirement
<b>Filter bag</b>		
Make	N.K. Filter	Design Requirement
Type	Polypropylene	Design Requirement
Pore Size	10 Micron	Design Requirement
<b>Actuator</b>		
Make	Rotex	Design Requirement
Type	Rotary	Design Requirement
<b>Pre Filter</b>		
Make	“Netfil”	Design Requirement
Type	Flange Type	Design Requirement
Pore Size	5 Micron	Design Requirement
Size (Inch)	24 x 24 x12 with Flange	Design Requirement
<b>Control Panel</b>		
MOC	SS304	Design Requirement
Temp Controller	Make : “L” & “T”	Design Requirement
Temp Indicator	Make : Radix	Design Requirement
Digital process Timer	Make : Radix	Design Requirement
Capacity	Make : Radix	Design Requirement
Earthing Relay	Make : Jayron	Design Requirement
Blower on/off Push Button	Make : “Technic”	Design Requirement
Bowl Lifting Selector Switch	Make : “Technic”	Design Requirement
Damper on/off Selector Switch	Make : “Technic”	Design Requirement
Manual Shaking Switch	Make : “Technic”	Design Requirement
Steam & Earthing Indicating lamp	Make : “Technic”	Design Requirement
Model	PT-100 Head Type Sensor	Design Requirement
<b>PU Wheels (8”)</b>	08 Nos.	Design Requirement
Make	Tex Mech Engineers	Design Requirement
<b>Exhaust Blower</b>		



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Make	Bright Flow Technologies Pvt.Ltd.	Design Requirement
Model	BFA-8	Design Requirement
Sr.No.	K-131487	Design Requirement
CFM	8000	Design Requirement
Static Pressure	65 MM WG	Process Requirement
Motor KW/HP	5.5/7.5	Process Requirement

**8.4 MATERIAL OF CONSTRUCTION:**

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



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

**8.5 SAFETY:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Joints</b>	Welding of joints without any welding burrs.	Safety Requirement
<b>Metal Parts</b>	All the metal parts should be properly grounded without any sharp edges.	Safety Requirement
<b>Leveling and Balancing</b>	Equipment should be properly balanced & leveled.	Safety Requirement
<b>Temperature Control</b>	Temperature gauge controls the temperature probe & gives input to the temp controller for steam flow or shut off.	Safety Requirement
<b>Inlet Air Flow</b>	Butterfly valve control quantity of inlet air as per user requirement.	Safety Requirement
<b>Low Air Pressure Switch</b>	If line pressure drops to less than set pressure (5 to 6 Kg/ sq.cm).the machine stops. Inflatable gasket of finger bag is set at 1.5 Kg/sq. cm. max	Safety Requirement
<b>Earth Safety Relay</b>	If the bowl is not in contact with both the probes the machine will not start.	Safety Requirement
<b>High Air Temperature</b>	System will turn off as temp exceeds set temperature.	Safety Requirement
<b>Over Load Relay</b>	Motor will tripped as it gets overloaded.	Safety Requirement

**8.5.1 Interlock Safety:**

<b>S.No.</b>	<b>SAFETY FEATURE</b>	<b>TRIGGERING CONDITION</b>
1.	Inlet temperature low	Inlet temperature has decreased below the negative allowed deviation.
2.	Inlet temperature high	Inlet temperature has increased above the positive allowed deviation.
3.	Outlet temperature low	Outlet temperature decreased below the negative allowed deviation.
4.	Outlet temperature high	Outlet temperature increased above the positive allowed deviation.
5.	Bed temperature low	Bed temperature decreased below the negative allowed.
6.	Bed temperature high	Bed temperature increased above the positive allowed deviation.



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

S.No.	SAFETY FEATURE	TRIGGERING CONDITION
7.	Auto cycle over	Auto cycle over as per predetermine set value of process time.
8.	Bag Tube pressure low	Check the possibility of Bag tube leakage fitting.
9.	Container lock limit switch not ok	Check the mounting position of container.

**8.6 VENDOR SELECTION:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<b>Selection of Vendor for supplying the FBD machine.</b>	Selection of Vendor is done on the basis of review of vendor.  Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment).	Process Requirement

**Reference:** (1) Specifications and Requirements as specified in P.O. and URS.  
(2) Operating and service manual for FBD.

**9.0 DOCUMENTS TO BE ATTACHED:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Purchase Order Copy.
- Any other relevant documents





**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

**13.0 ABBREVIATIONS:**

AISI	:	American Iron & Steel Institute
C.I	:	Cast Iron
cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
db	:	Decibel
DQ	:	Design Qualification
FBD	:	Fluid Bed dryer
GA	:	General Arrangement
GB	:	General Block
HEPA	:	High Efficiency Particulate Air
HP	:	Horse Power
Hr	:	Hour
Kg	:	Kilogram
MCB	:	Miniature Circuit Break
mm	:	Millimeter
MMI	:	Man Machine Interface
MOC	:	Material of Construction
NA	:	Not Applicable
P & ID	:	Piping and Instrumentation Diagram
QA	:	Quality Assurance
RH	:	Relative Humidity
Sr.	:	Senior
SS	:	Stainless Steel
STD	:	Standard
URS	:	User requirement specification
OD	:	Oral Solid Dosage Form



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLUID BED DRYER**

**14.0 REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			