



**PERFORMANCE  
REQUALIFICATION REPORT  
FOR  
FLUID BED DRYER**

**EQUIPMENT ID: .....**

**LOCATION: GRANULATION AREA  
(.....BLOCK)**

<b>LOCATION</b>	
<b>DATE OF REQUALIFICATION</b>	
<b>SUPERSEDE REPORT No</b>	



**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**  
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**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

**1.0 REPORT PRE -APPROVAL :**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (QUALITY CONTROL)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			



**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

**2.0 OBJECTIVE:**

- 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 FBD being used at .....
- This Protocol will define the methods and documentation used to re-qualify the FBD 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 Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Authorization of the Performance Qualification Protocol.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Protocol Activity</li><li>• Monitoring of Performance Qualification activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of the Protocol.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>
<b>Quality Control</b>	<ul style="list-style-type: none"><li>• Review of Protocol</li><li>• Analytical Support (Analysis)</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of the Protocol.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>



**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	<b>Fluid Bed Dryer</b>
<b>Manufacturer's Name</b>	
<b>Location of Installation</b>	<b>Granulation Area</b>
<b>Equipment ID No.</b>	

**6.0 PRE-QUALIFICATION REQUIREMENTS:**

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 PQ commencing.

**6.1 SYSTEM PRE-REQUISITES:**

Verify that the DQ/IQ/OQ of the Fluid Bed Dryer has been executed and approved.

Verify that the Operating and Cleaning SOP of the Fluid Bed Dryer has been prepared.

<b>S.No.</b>	<b>DOCUMENT NAME</b>	<b>DOCUMENT/ SOP No.</b>	<b>COMPLETED (YES/NO)</b>	<b>CHECKED BY (PRODUCTION) (SIGN/DATE)</b>	<b>VERIFIED BY (QA) (SIGN/DATE)</b>
1.	DQ Protocol				
2.	IQ Protocol				
3.	OQ Protocol				
4.	Operating Procedure SOP				
5.	Cleaning Procedure SOP				



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QUALITY ASSURANCE DEPARTMENT

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**7.0 TRAINING RECORD:**

**SUPERVISORY STAFF**

S.No.	Name of Trainee	Designation	Training on protocol is given (Yes/No)	Signature of Trainee	Checked by (Sign/Date) (QA)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Name of the Trainer: \_\_\_\_\_

Inference:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Reviewed By (Sign/Date) \_\_\_\_\_  
(Manager QA)



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**8.0 PROPOSED PRODUCT BATCH INFORMATION:**

S.No.	Product Name	Batch no.	Batch size	Mfg date	Expiry date

**Compiled By:** \_\_\_\_\_

(QA)

**Sign/Date:**

**Inference:**

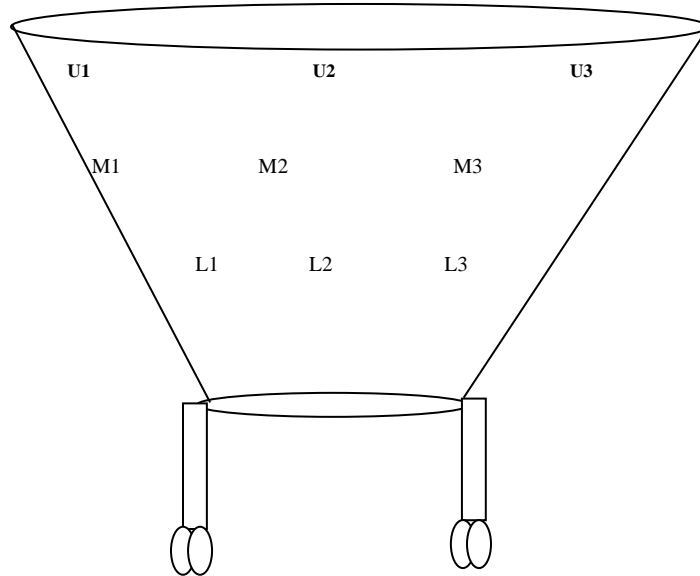
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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** \_\_\_\_\_



**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

**9.0 SAMPLING LOCATIONS:**



**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.





**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

**10.0 TESTS & RESULTS:**

**Moisture content result**

<b>Equipment</b>	<b>FLUID BED DRYER</b>	<b>Equipment ID</b>	
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➤ The moisture content of all three batch pooled sample withdrawn from upper, middle & lower side.

**(I) Product Name:** \_\_\_\_\_ **Batch No.:** \_\_\_\_\_

**Sampling Location (FBD Bowl):** U<sub>1</sub>, U<sub>2</sub>, U<sub>3</sub>, M<sub>1</sub>, M<sub>2</sub>, M<sub>3</sub> & L<sub>1</sub>, L<sub>2</sub>, L<sub>3</sub>

\*Result of drying was found to be follow:-

S.No.	Timing	Product Name	Batch no.	Inlet Temperature (set )	Outlet Temperature (set)	Inlet Temperature (observed )	Outlet Temperature (observed)
1.	After- ___ Minute						
2.	After- ___ Minute						
3.	After- ___ Minute						

S.No	Sample- timing	Moisture content %									Acceptance Limit	Done By
		Upper (Top) (Pooled sample from three Location)			Middle (Pooled sample from three Location)			Lower (Pooled sample from three Location)				
1.	After ___ Minute	U1	U2	U3	M1	M2	M3	L1	L2	L3		
2	After ___ Minute	U1	U2	U3	M1	M2	M3	L1	L2	L3		
3	After ___ Minute	U1	U2	U3	M1	M2	M3	L1	L2	L3		

**Compiled By:** \_\_\_\_\_

**(QA)**

**Sign/Date:**

**Inference:**.....

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**Reviewed By**  
**(Manager QA)**

**Sign/Date:** \_\_\_\_\_



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(II) **Product Name:** \_\_\_\_\_ **Batch No.:** \_\_\_\_\_

**Sampling Location (FBD trolley):** U<sub>1</sub>, U<sub>2</sub>, U<sub>3</sub>, M<sub>1</sub>, M<sub>2</sub>, M<sub>3</sub> & L<sub>1</sub>, L<sub>2</sub>, L<sub>3</sub>

\*Result of drying was found to be follow:-

S.No.	Timing	Product Name	Batch no.	Inlet Temperature (set )	Outlet Temperature (set)	Inlet Temperature (observed )	Outlet Temperature (observed)
1.	After- ___ Minute						
2.	After- ___ Minute						
3.	After- ___ Minute						

Sr. No.	Sample- timing	Moisture content %									Acceptance Limit	Done By
		Upper (Top) (Pooled sample from three Location)			Middle (Pooled sample from three Location)			Lower (Pooled sample from three Location)				
		U1	U2	U3	M1	M2	M3	L1	L2	L3		
1.	After- ___ Minute											
2	After- ___ Minute											
3	After ___ Minute											

**Compiled By:** \_\_\_\_\_

(QA)

**Sign/Date:**

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** \_\_\_\_\_



**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

**(III) Product Name:** \_\_\_\_\_ **Batch No.:** \_\_\_\_\_

**Sampling Location (FBD trolley):** U<sub>1</sub>, U<sub>2</sub>, U<sub>3</sub>, M<sub>1</sub>, M<sub>2</sub>, M<sub>3</sub> & L<sub>1</sub>, L<sub>2</sub>, L<sub>3</sub>

\*Result of drying was found to be follow:-

S.No.	Timing	Product Name	Batch no.	Inlet Temperature (set)	Outlet Temperature (set)	Inlet Temperature (observed)	Outlet Temperature (observed)
1.	After- ___ Minute						
2.	After- ___ Minute						
3.	After- ___ Minute						

S.No.	Sample- timing	Moisture content %									Acceptance Limit	Done By
		Upper (Top) (Pooled sample from three Location)			Middle (Pooled sample from three Location)			Lower (Pooled sample from three Location)				
1.	After- ___ Minute	U1	U2	U3	M1	M2	M3	L1	L2	L3		
2	After- ___ Minute	U1	U2	U3	M1	M2	M3	L1	L2	L3		
3	After ___ Minute	U1	U2	U3	M1	M2	M3	L1	L2	L3		

**Compiled By:** \_\_\_\_\_

**(QA)**

**Sign/Date:**

**Inference:**.....  
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.....

**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** \_\_\_\_\_



**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

**11.0 DOCUMENTS ATTACHED:**

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**12.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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**13.0 NON COMPLIANCE:**

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**14.0 CHANGE CONTROL, IF ANY:**

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**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

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

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**16.0 CONCLUSION:**

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**17.0 RECOMMENDATION:**

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**PERFORMANCE QUALIFICATION REPORT FOR FLUID BED DRYER**

**18.0 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
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
mm	:	Millimeter
Amp.	:	Ampere



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**19.0 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)			