



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> In-process Checks of FBD	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down a procedure for In process checks of FBD.

### 2.0 SCOPE:

2.1 This SOP is applicable for the In process checks of FBD in the production area.

### 3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Operation as per SOP  
3.2 Production Officer/ Executive : Checking Operation & In process as per SOP  
3.3 IPQA Person : On line Process Confirmation as per SOP  
3.4 Head Production : SOP Compliance

### 4.0 DEFINITION (S):

4.1 NA

### 5.0 PROCEDURE:

- 5.1 Check the FBD bag integrity before and after drying and record it in the respective BMR.  
5.2 Operates the FBD as per their respective SOP.  
5.3 Place the FBD bowl containing wet milled granules under the retarding chamber and fit it to the retarding chamber by operating the control panel.  
5.4 Reshuffle the granules after every drying cycle completed and record it in the respective BMR.  
5.5 At the time of drying monitor the inlet, bed and out let temperature and record it at every 30 minutes interval in the respective BMR.  
5.6 LOD shall be periodically monitored as protocol base during validation and after achieving outlet temperature. So in non validation, LOD checks during routine manufacturing, the LOD shall be recorded once outlet achieved.

### 6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol  
6.2 SOP : Standard Operating Procedure  
6.3 BMR : Batch Manufacturing Record  
6.4 HMI : Human Machine Interface



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### 7.0 REFERENCES (S):

7.1 NA

### 8.0 ANNEXURE (S)

Annexure No.	Title of Annexure	Format No.	Mode of execution
Annexure-I	In process checks at FBD		Logbook

### 9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled copy (s)** : Production department (02) and Quality Assurance (01)

9.3 **Reference copy (s)** : Production department (05)

### 10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details of Revision	Effective Date
01	00		New SOP	NA	



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### ANNEXURE I

#### In-Process Checks at FBD

<b>Product Name:</b>							<b>Batch No.</b>		
<b>Record the parameters at every 30 minutes interval.</b>									
S.No.	Time	Temperature			Shuffling \$	Sieve Integrity #		Done By	Checked By
		Inlet	Bed	Outlet		Before	After		

\$ Reshuffle the granules after drying cycle completed and put '√' mark after completion.  
 # Sieve integrity check done before start the drying process and after completion of drying process and put '√' mark after completion.