

PHARMA DEVILS

PRODUCTION DEPARTMENT

| STANDARD OPERATING PROCEDURE | | | | |
|---|-----------------|--|--|--|
| Department: Production | SOP No.: | | | |
| Title: Cleaning and challenge test of Solid Flow Monitor for Fluidized Bed Dryer | Effective Date: | | | |
| Supersedes: Nil | Review Date: | | | |
| Issue Date: | Page No.: | | | |

1.0 **OBJECTIVE**:

To lay down the procedure for Cleaning and challenge test of Solid Flow Monitor for Fluidized Bed Dryer.

2.0 SCOPE:

This procedure is applicable to Cleaning and challenge test of Solid Flow Monitor for Fluidized Bed Dryer in granulation area.

3.0 **RESPONSIBILITY:**

Production: Technical Associate/Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance

4.0 PROCEDURE:

4.1 Checks and precautions:

- 4.1.1 Check the integrity of Dutch mesh of product container before and after each usage.
- 4.1.2 Ensure that the earthing probe is properly connected to the equipment.
- 4.1.3 Ensure that incoming main air pressure is not less than 6 kg/cm² during entire operation.

4.2 Cleaning procedure of sensors of Solid Flow monitor:

- 4.2.1 Loosen the bolt/clamp fitted with SFM sensor.
- 4.2.2 Take out the sensor carefully and clean the sensor.
- 4.2.3 Clean the sensor rod along with Teflon base thoroughly using dry lint free cloth.
- 4.2.4 Assemble the sensor in its original position by tightening the bolt/clamp.
- 4.2.5 During assembling of sensor, ensure that the cable attached to the sensor should not be twisted.
- 4.2.6 Ensure that the sensor is tightly fitted at the correct position and is not touching any other part.
- 4.2.7 Frequency: Before and after Challenge test of Solid flow Monitor

4.3 Challenge test for Solid flow Monitor:

4.3.1 Start the challenge test as per schedule after completion of batch and before changeover.



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- 4.3.2 Material like Starch / Talc / Micro-crystalline Cellulose can be taken for Challenge test.
- 4.3.3 Issue the required quantity of materials for challenge test from raw material stores as per requirement.
- 4.3.4 Take approximately 250 gm of material for challenge tests and record in Annexure I.
- 4.3.5 Challenge test should be carried out in such a way that challenge material should go through exhaust and should come in contact with SFM sensor.
- 4.3.6 During challenge test, follow the below procedure,Remove the finger bag and take holding ring to the up position.
- 4.3.7 Place the materials in the FBD bowl and keep FBD bowl in its original position and set the FBD in auto mode.
- 4.3.8 Start FBD as per the operating procedure and allow the challenge material to go through exhaust.
- 4.3.9 Ensure that SFM sensor sense the material flow and trips the FBD within 5 to 10 seconds after exhaust blower in full speed, if not, repeat the above process with double quantity of materials.
- 4.3.10 If still SFM sensor fails to sense the material going through exhaust, inform engineering department.
- 4.3.11 After completion of successful challenge test, reset the SFM sensor till all challenge test materials goes out through exhaust and FBD runs continuously without tripping in empty run.
- 4.3.12 After completion of challenge test, clean the sensor as per above cleaning procedure.

4.4 Frequency of Challenge test for Solid flow Monitor:

- 4.4.1 Challenge tests to be performed on every 14 + 2 days.
- 4.4.2 In case of campaign production during the schedule, challenge test to be performed after completion of product.
- 4.4.3 If FBD is not running for many days, then challenge test to be done before starting product.
- 4.4.4 Record 'SFM Challenge test' in Sequential log of individual equipment and also in Annexure I.



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4.4.5 Reconciliation of material for SFM challenge test is to be done in Annexure - II at the end of every month.

5.0 ANNEXURE (S):

Annexure—I: Utilization record of Challenges materials.

Annexure-II: Reconciliation for Challenges materials.

6.0 REFERENCE (S):

SOP: Preparation, Approval, Distribution control, revision and destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

BMR : Batch Manufacturing Record.

QA : Quality Assurance

FBD: Fluidized Bed Dryer.

SFM: Solid Flow Monitor.

Gm : Gram

REVISION CARD

| S.No. | REVISION No. | REVISION DATE | DETAILS OF REVISION | REASON (S)FOR REVISION | REFERENCE CHANGE CONTROL No. |
|-------|--------------|------------------|---------------------|---------------------------|------------------------------------|
| 1 | 00 | | | New SOP | |