PERFORMANCE QUALIFICATION PROTOCOL FOR SOLID FLOW MONITOR CHALLENGE TEST

LOCATION	
SUPERSEDES PROTOCOL CUM REPORT No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR SOLID FLOW MONITOR CHALLENGE TEST	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	**PERFORMANCE QUALIFICATION PROTOCOL FOR SOLID FLOW MONITOR CHALLENGE TEST**	**PROTOCOL No.:**

1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined Acceptance Criteria.

3.0 SCOPE:

- The Protocol covers all Aspects of challenge Test of Solid Flow Monitor for the **Fluid Bed Dryer/Fluid Bed Processor** installed in the Granulation area.
- This Protocol will define the methods and documentation used to qualify the Solid Flow Monitor for Performance Qualification.

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.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Review, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 Reason for Validation

- Validate the procedure of solid flow monitor Challenge test.

6.0 Site of Study:

- Granulation area.

7.0 Training Details:

Fill the training record in the Solid Flow monitor challenge test for those performing as per protocol.

Topic of Training: ……..

S.No.	Name of Trainee	Designation	Signature

Training Given By:
Sign & Date: ……

Inference:

……

……

……

……

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

8.0 Methodology:

Procedure 1:

- Lowering the finger bag of FBD/FBP and put 1.0 kg fine powder (Starch) in the top of bag.
- Seal the bag and bowl.
- Open the damper 35% or Set the Blower 1500 RPM than start the FBD.

Procedure 2:

- Lowering the finger bag of FBD/FBP and put 0.5 kg fine powder (Starch) in the top of bag.
- Seal the bag and bowl.
- Open the damper 60% or Set the Blower 2500 RPM than start the FBD.

9.0 Master Document Verification:

- Verify the procedure of Protocol.

10.0 ACCEPTANCE CRITERIA:

- SFM will trip

11.0 VALIDATION / RE–VALIDATION CRITERIA

- Initially

12.0 FREQUENCY OF VALIDATION:

- If any modification of challenge or FBD/FBP operating Procedure.

13.0 DEVIATIONS FROM PRE-DEFINED SPECIFICATION, IF ANY

- In case of any deviation observed during Solid Flow Monitor Challenge test, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on properties of product & prepare final conclusion.

14.0 CHANGE CONTROL, IF ANY

- If any change control is required during Solid Flow Monitor Challenge test, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on properties of product & prepare final conclusion.

15.0 CONCLUSION

- Solid Flow Monitor Challenge test shall be written on Solid Flow Monitor Challenge test Report.
- Clearly stating the achievement or non-compliance of the acceptance criteria, effect of the deviations made during the mapping and in case of failure, investigation carried out and their findings.

16.0 RECOMMENDATION

- Recommendation shall be made on the basis of review made according to conclusion derived by representative of each concerned department i.e. QA, Engineering, and Production.

17.0 REFERENCES:

- Vendor Procedure.
- Literature Document of Solid Flow Monitor.

18.0 DOCUMENT TO BE ATTACHED:

- List of SFM sensor installed .

19.0 ABBREVIATIONS:

QA	:	Quality Assurance
PQ	:	Performance Qualification
FBD	:	Fluid Bed Dryer
FBP	:	Fluid Bed Processor
SFM	:	Solid Flow Monitor