



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
SOLID FLOW MONITOR CHALLENGE TEST**

PROTOCOL No.:

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DATE OF QUALIFICATION

SUPERSEDES REPORT No.

NIL



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REPORT CONTENTS

S.No.	TITLE	PAGE No.
1.0	Report Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Training Details	5
6.0	Master Document Verification	6
7.0	Location Details	6
8.0	Critical parameters	6-7
9.0	References	8
10.0	Documents to be attached	8
11.0	Deviation from Pre-Defined Specifications (If any):	8
12.0	Change Control (if any)	8
13.0	Review (Inclusive of Follow Up Action, If Any)	8
14.0	Conclusion	8
15.0	Recommendation	9
16.0	Abbreviations	9
17.0	Report Post Approval	10



PHARMA DEVILS

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1.0 REPORT PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			



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2.0 OBJECTIVE:

- The main objective of solid flow monitor challenge test study report is to establish that standard procedure for performance of solid flow monitor challenge test in routine practice.

3.0 SCOPE:

- This report is applicable for solid flow monitor challenge test in the **Granulation area**.

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 Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Initiation, Review, Compilation of the Report.• Post Approval of Qualification Report after Execution.• Co-ordination with Production and Engineering to carryout SFM challenge test activity.• Monitoring of SFM challenge test activity.
Production	<ul style="list-style-type: none">• Approval of the Report.• Assist in the verification of Critical Process Parameters.• Post Approval of SFM challenge test Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of the Report.• Assist in the Preparation of the Report.• To co-ordinate and support the Activity.• Post approval of report after Execution.



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6.0 MASTER DOCUMENT VERIFICATION :

S.No.	Description of Control	Document Ref. No.	Status / Remarks
1.	Verify the procedure of Protocol		

7.0 LOCATION DETAILS :

Name of Area	Granulation Area
Floor	
Block	

8.0 CRITICAL PARAMETERS :-

8.1 OBSERVATION REPORT:

8.1.1 SFM challenge test:

S.No.	SFM ID No.	Location	Summary Report			
			Date of Test	Procedure 1 Observation	Date of Test	Procedure 2 Observation

Acceptance Criteria: SFM will trip

Verified By:

Sign & Date.....

Remark:

.....
.....
.....

**Reviewed By:
(Manager QA)**

Sign & Date.....



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9.0 REFERENCES

The Principle Reference is the following:

- Solid Flow Monitor Challenge Test Protocol.

10.0 DOCUMENTS TO BE ATTACHED

- If any document required.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATIONS (IF ANY):

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12.0 CHANGE CONTROL (IF ANY):

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATION:

- CQA : Corporate Quality Assurance
- Ltd. : Limited
- No. : Number
- Pvt. : Private
- QA : Quality Assurance
- SFM : Solid Flow Monitor



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17.0 REPORT POST –APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			