PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING TANK

EQUIPMENT ID. No.	
LOCATION	**MANUFACTURING ROOM**
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING TANK	PROTOCOL No.:

REPORT CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING TANK	PROTOCOL No.:

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)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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 the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The scope of this qualification protocol is limited to qualification of Manufacturing Tank Installed in Manufacturing Room.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the execution of Performance Qualification Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Approval and Compilation of the Performance Qualification Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Quality Control	• Analytical Support (Microbial Testing/ chemical Analysis).
Engineering	• Reviewing of qualification report for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule. • Post Approval of Performance Qualification Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Manufacturing Tank
Equipment	
Manufacturer's Name	Pharmatech Process Equipments
Model	
Location of Installation	Manufacturing Room

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 Training Record of Validation Team:

All the persons involved in the execution of qualification activity must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working.

S.No	Name of Trainee	Designation	Trainee (Sign. / Date)	*Training Evaluation (Satisfactory / Not Satisfactory)
Training Given By: Sign & Date				

**Note: Training evaluation shall be done on the basis of oral assessment.*

6.2 Verification of Documents:

Verify that the DQ/IQ/OQ of manufacturing vessel has been executed and approved.

Verify that SOP for Operating, Cleaning and Preventive Maintenance of the manufacturing vessel has been prepared.

S.No.	Document Name	Completed (Yes/No)	Checked By Engineering Sign/Date	Verified By (QA) Sign/Date
1.	Executed and approved DQ Protocol Cum Report			
2.	Executed and approved IQ Protocol Cum Report			
3.	Executed and approved OQ Protocol Cum Report			
4.	Approved PQ Protocol			
5.	SOP for Operating, Cleaning of the manufacturing vessel			
6.	SOP for Preventive Maintenance of the manufacturing vessel			

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.0 TESTS AND CHECKS :

7.1 Equipment Volumetric Minimum Capacity Test and Uniformity of Mixing at Minimum RPM

Name of Equipment		**Capacity of Vessel**	
Make		**Equipment Id No.**	
B.no. Of NaCl		**Concentration Used**	
Stirrer RPM			

Test For	Date of Test	Sample Location	Critical variables	Observation	Acceptance Criteria	Complies (Yes/No)
400 Ltr.		Top	Assay		0.882% W/V – 0.918%W/V	
		Bottom	Assay			
		% RSD of Assay			≤ 2%	

Checked By
Production
(Sign/Date):……..

Verified By
Quality Assurance
(Sign/Date):……..

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.2 Equipment Volumetric Minimum Capacity Test and Uniformity of Mixing at Maximum RPM

Name of Equipment		**Capacity of Vessel**	
Make		**Equipment Id No.**	
B.no. Of NaCl		**Concentration Used**	
Stirrer RPM			

Test For	Date of Test	Sample Location	Critical variables	Observation	Acceptance Criteria	Complies (Yes/No)
400 Ltr.		Top	Assay		0.882% w/v – 0.918% w/v	
		Bottom	Assay			
		% RSD of Assay			≤ 2%	

Checked By
Production
(Sign/Date):……..

Verified By
Quality Assurance
(Sign/Date):……..

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.3 Equipment Volumetric Maximum Capacity Test and Uniformity of Mixing at Minimum RPM

Name of Equipment		**Capacity of Vessel**	
Make		**Equipment Id No.**	
B.no. Of NaCl		**Concentration Used**	
Stirrer RPM			

Test For	Date of Test	Sample Location	Critical variables	Observation	Acceptance Criteria	Complies (Yes/No)
2000 Ltr.		Top	Assay		0.882% w/v – 0.918%w/v	
		Bottom	Assay			
		% RSD of Assay			≤ 2%	

Checked By
Production
(Sign/Date):……..

Verified By
Quality Assurance
(Sign/Date):……..

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.4 Equipment Volumetric Maximum Capacity Test and Uniformity of Mixing at Maximum RPM

Name of Equipment		**Capacity of Vessel**	
Make		**Equipment Id No.**	
B.no. Of NaCl		**Concentration Used**	
Stirrer RPM			

Test For	Date of Test	Sample Location	Critical variables	Observation	Acceptance Criteria	Complies (Yes/No)
2000 Ltr.		Top	Assay		0.882% w/v – 0.918%w/v	
		Bottom	Assay			
		% RSD of Assay			≤ 2%	

Checked By
Production
(Sign/Date):……..

Verified By
Quality Assurance
(Sign/Date):……..

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

Tests or checks	Executed [Yes/No]	Remark
Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Minimum RPM		
Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Minimum RPM		
Equipment Volumetric Maximum Capacity Test and Verification of Uniformity of Mixing at Maximum RPM		
Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Maximum RPM		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

9.0 DOCUMENTS ATTACHED:

- Test Report from QC lab
- Any other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, 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 ABBREVIATIONS:

%	:	Percentage
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
LTD.	:	Limited
MFT	:	Manufacturing vessel
Nacl	:	Sodium Chloride
No.	:	Number
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
PVT	:	Private
RPQ	:	Report performance qualification
RSD	:	Relative standard deviation
SOP	:	Standard Operating Procedure

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)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			