PERFORMANCE QUALIFICATION REPORT FOR MULTI-MIX MANUFACTURING PLANT MANUFACTURING PLANT

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR MULTI-MIX MANUFACTURING PLANT	PROTOCOL No.:

REPORT CONTENTS

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 (PRODUCTION)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To objective of this document is to carry out performance Qualification of multi mix manufacturing plant Installed in manufacturing Line.
- To provide documented evidence that the Equipment is performing as per the parameter defined in Performance Qualification of and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- 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 document is limited to carry out the performance Qualification of Multi- mix manufacturing plant.

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.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Quality Control	• Review of performance Qualification report. • Analytical Support (Microbiological Testing/Chemical Analysis). • Post review of Performance Requalification Report after Execution.
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	Multi mix manufacturing Plant			
Equipment				
Capacity	**Type of Vessel**	**Working Capacity**	**Gross capacity**	**ID**
	Wax Phase vessel	30 Liters	40Liters	
	Water Phase vessel	30 Liters	40Liters	
	Main manufacturing vessel	60 Liters	75 Liters	
Manufacturer's Name				
Supplier's Name				
Location of Installation	Manufacturing Line			

6.0 SYSTEM DISCRIPTION:

To design and manufacture multi mix plant for processing of ointment / cream / gels / lotion as per product safety, cGMP guideline and to provide assurance that the equipment is manufactured as per the URS and it complies with the scope of supply.

1. Multi mixer manufacturing vessel
2. Water Phase Vessel
3. Wax phase vessel
4. Transfer pump
5. Electric control panel
6. Vacuum pump
7. Utility system
8. Batch storage vessel working platform
9. Homogenizer
10. Meter in jump

Multi Mixer manufacturing vessel:

It consists of cylindrical shell and jacketed vessel. It is fitted with the top mounted SS 316 shaft with anchor having baffles and Teflon scrappers moving in a clockwise direction. One more baffles system is mounted in the inner side of the vessel. The vessel is provided with pressure release vent, safety valve rupture disc, gauge and a temperature sensor with digital display. The vessel is provided with bottom homogenizer and unloading of finished product to storage vessel using lobe pump. The vessel is also provided with steam and cooling water to the jacketed tank.

The vessel is also provided with light glass, sight glass, charge hole and hand hold on top dished end.

High speed homogenizer is installed at the manufacturing vessel. It is a silverson type homogenizer and consists of slit sleeve type SS 316 blade and rotates at 2800 RPM.

Wax phase Vessel:

It is fitted with bottom mounted stirrer coupled to SS 316 shaft with agitator, pressure gauge, vent valve, safety valve rupture disc, and a temperature sensor with digital display. It is provided with bottom outlet connected to manufacturing vessel through a conical filter having SS mesh screen of 100# filter of melted waxes. It is also provided with the steam supply to the jacket.

Water Phase vessel:

It is fitted with bottom mounted stirrer coupled to SS 316 shaft with agitator, pressure gauge, vent valve, safety valve rupture disc, and a temperature sensor with digital display. It is provided with bottom outlet connected to manufacturing vessel through a conical filter having SS mesh screen of 100# filter of melted waxes. It is also provided with the steam supply to the jacket.

Utility system:

A utility pendant is provided to bring the utility lines from the service floor to the platform so as to run the utility line below the platform.

There is a manual mode of operation for manufacturing plant-400 kg. For manual mode selector switches are provided on control panel to control the parameter.

- Water inlet : 1” dia. TC flanged end.
- Water outlet : 1” dia. TC flanged end.
- Cooling water inlet : 1” dia. TC flanged end.
- Cooling water outlet : 1” dia. TC flanged end.

7.0 REASON FOR QUALIFICATION:

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8.0 SITE OF STUDY:

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9.0 FREQUENCY OF QUALIFICATION:

- Periodic re-qualification at frequency of every two years.
- After any major breakdown or after major modification
- After Change of Location.

10.0 PRE– QUALIFICATION REQUIREMENTS:

Verification for availability, Completeness and approval status of all the required relevant documents shall be done.

10.1 VERIFICATION OF DOCUMENTS:

Before start of performance qualification activity, below mentioned documents shall be verified and recorded in below table.

S. No.	Document Name	Completed (Yes/No)	Checked By (Production) 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.	Approved SOP for Operation & Cleaning of multi -mix manufacturing plant			
6.	SOP for Preventive Maintenance of multi-mix manufacturing plant			

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

10.2 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.*

11.0 TESTS & CHECKS:

11.1 Equipment Volumetric Minimum Capacity Test and Uniformity of Mixing at Minimum RPM & Maximum RPM: Wax Phase Vessel

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Minimum RPM			

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

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Maximum RPM			

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

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(Sign/Date):……..

Verified By
QA
(Sign/Date):……..

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

11.2 Equipment Volumetric Maximum Capacity Test and Uniformity of Mixing at Minimum RPM & Maximum RPM: Wax Phase Vessel

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Minimum RPM			

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

Name of equipment		**Capacity of vessel**	
Make		**Equipment ID No.**	
Concentration used		**Batch no. of NaCl**	
Maximum RPM			

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

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Inference:

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Reviewed By
Manager QA
Sign/Date: ……

11.3 Equipment Volumetric Minimum Capacity Test and Uniformity of Mixing at Minimum RPM & Maximum RPM: Water Phase Vessel

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Minimum RPM			

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

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Maximum RPM			

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

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Verified By
QA
(Sign/Date):…….

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Reviewed By
Manager QA
Sign/Date: ……

11.4 Equipment Volumetric Maximum Capacity Test and Uniformity of Mixing at Minimum RPM & Maximum RPM: Water Phase Vessel

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Minimum RPM			

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

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Maximum RPM			

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

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(Sign/Date):……..

Verified By
QA
(Sign/Date):…….

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

11.5 Equipment Volumetric Minimum & Maximum Capacity (in liters) Test by Physical Verification, Chemical Assay Method and Uniformity of Solution at Minimum RPM: Main Mixer Vessel

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Minimum RPM			

a. Equipment Volumetric Capacity (In Liters) Test (Physical Verification):

Test For	Date of Test	Observation on load cell in Ltr.	Acceptance Criteria	Complies (Yes/No)
20 Ltr.			19.94 to 20.06 Ltr.	
60 Ltr.			59.82 to 60.18 Ltr.	

b. Equipment Volumetric Capacity (In Liters) Test (Chemical Assay Method):

Test For	Date of Test	Weight of NaCl	Sample Location	Observation	Acceptance Criteria	Complies (Yes/No)
20 Ltr.			Top		0.882% W/V – 0.918%W/V	
			Bottom			
60 Ltr.			Top			
			Bottom			

c. Test for verification of uniformity of mixing:

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

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Production
(Sign/Date):……..

Verified By
QA
(Sign/Date):…….

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

11.6 Equipment Volumetric Minimum & Maximum Capacity (in liters) Test by Physical Verification, Chemical Assay Method and Uniformity of Solution at Maximum RPM: Main Mixer Vessel

Name of equipment		**Capacity of vessel**	
Make		**Equipment Id no.**	
Concentration used		**Batch no. of NaCl**	
Maximum RPM			

a. Equipment Volumetric Capacity (In Liters) Test (Physical Verification):

Test For	Date of Test	Observation on load cell in Ltr.	Acceptance Criteria	Complies (Yes/No)
20 Ltr.			19.94 to 20.06 Ltr.	
60 Ltr.			59.82 to 60.18 Ltr.	

b. Equipment Volumetric Capacity (In Liters) Test (Chemical Assay Method):

Test For	Date of Test	Weight of NaCl	Sample Location	Observation	Acceptance Criteria	Complies (Yes/No)
20 Ltr.			Top		0.882% W/V – 0.918%W/V	
			Bottom			
60 Ltr.			Top			
			Bottom			

c. Test for verification of uniformity of mixing:

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

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Production
(Sign/Date):……..

Verified By
QA
(Sign/Date):……..

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

11.7 CHECK LIST OF ALL TESTS & CHECKS

S. No.	Name of Test or checks	Execution (Yes / No)	Remarks
1.	Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Minimum RPM (Wax Phase)		
2.	Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Maximum RPM (Wax Phase)		
3.	Equipment Volumetric Maximum Capacity Test and Verification of Uniformity of Mixing at Minimum RPM (Wax Phase)		
4.	Equipment Volumetric Maximum Capacity Test and Verification of Uniformity of Mixing at Maximum RPM (Wax Phase)		
5.	Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Minimum RPM (Water Phase)		
6.	Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Maximum RPM (Water Phase)		
7.	Equipment Volumetric Maximum Capacity Test and Verification of Uniformity of Mixing at Minimum RPM (Water Phase)		
8.	Equipment Volumetric Maximum Capacity Test and Verification of Uniformity of Mixing at Maximum RPM(Water Phase)		
9.	Equipment Volumetric Minimum Capacity Test (Physical Verification & Chemical Assay method) and Verification of Uniformity of Mixing at Minimum RPM (Main Mixer Vessel)		
10.	Equipment Volumetric Minimum Capacity Test (Physical Verification & Chemical Assay method) and Verification of Uniformity of Mixing at Maximum RPM (Main Mixer Vessel)		
11.	Equipment Volumetric Maximum Capacity Test (Physical Verification & Chemical Assay method) and Verification of Uniformity of Mixing at Minimum RPM (Main Mixer Vessel)		
12.	Equipment Volumetric Maximum Capacity Test (Physical Verification & Chemical Assay method) and Verification of Uniformity of Mixing at Maximum RPM (Main Mixer Vessel)		

12.0 REFERENCE:

- SOP for "Operation & Cleaning of Multi Mix Manufacturing Plant".
- Operational Qualification Protocol cum Report of Multi Mix Manufacturing Plant.

13.0 DOCUMENTS ATTACHED:

- Analytical reports
- Any other relevant documents

14.0 NON COMPLANCE:

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15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION , IF ANY:

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16.0 CHANGE CONTROL, IF ANY:

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

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18.0 CONCLUSION :

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RECOMMENDATION :

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19.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
LTD.	:	Limited
No.	:	Number
MMP	:	Multi-mix manufacturing plant
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
PVT	:	Private
RPQ	:	Report performance qualification
SOP	:	Standard Operating Procedure

20.0 REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			