



**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
JACKETED MANUFACTURING
TANK
MANUFACTURING LINE**

EQUIPMENT ID. No.	
LOCATION	Manufacturing line
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL



**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

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	Equipment details	6
6.0	Pre-requalification requirements	6
7.0	Tests & checks	7
8.0	Check list of all tests & checks	14
9.0	Documents to be attached	14
10.0	Non-compliance	14
11.0	Deviation from pre defined specification	15
12.0	Change control	15
13.0	Review (inclusive of follow up action, if any)	15
14.0	Conclusion	15
15.0	Recommendation	15
16.0	Abbreviation	16
17.0	Report post approval	17



**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

1.0 REPORT PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

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 Area, Lotion Line.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.




**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Performance Qualification Activity.• Post Approval of Performance Qualification Report after Execution.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbial Testing/ chemical Analysis).
Engineering	<ul style="list-style-type: none">• 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.

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

5.0 EQUIPMENT DETAILS:

Equipment Name	Manufacturing Tank
Equipment	
Manufacturer's Name	Punchtab
Model	cGMP
Location of Installation	Manufacturing Line

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.

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			

7.0 TESTS AND CHECKS :

7.1 Equipment Volumetric Capacity (In Liters) Test:

Name of equipment		Capacity of vessel	
Make		Equipment id no.	

Date of test	Trial no.	Acceptance criteria	Observation
		150 liter ± 0.3% (149.55 to150.45)	
		450 liter ± 0.3% (448.65 to 451.35)	
		150 liter ± 0.3% (149.55 to150.45)	
		450 liter ± 0.3% (448.65 to 451.35)	
		150 liter ± 0.3% (149.55 to150.45)	
		450 liter ± 0.3% (448.65 to 451.35)	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

.....

Reviewed By
Manager QA
Sign/Date:

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

7.2 Equipment Volumetric Capacity (In Liters) Test by chemical assay method at Minimum Speed of stirrer (15.0 Hz):

Trial No.:

Name of equipment		Capacity of vessel	
Make		Equipment Id no.	

Date	Volume of tank	Weight of NaCl	Results			Acceptance criteria
			Description	pH	Assay	
	150 Ltr.					0.882% to 0.912%
	250 Ltr.					
	350 Ltr.					
	450 Ltr.					

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date.....

Inference:

Reviewed By
Manager QA
Sign/Date:

7.3 Equipment Volumetric Capacity (In Liters) Test by chemical assay method at Maximum Speed of stirrer (30.0 Hz):

Trial No.:

Name of equipment		Capacity of vessel	
Make		Equipment Id no.	

Date	Volume of tank	Weight of NaCl	Results			Acceptance criteria
			Description	pH	Assay	
	150 Ltr.					0.882% to 0.912%
	250 Ltr.					
	350 Ltr.					
	450 Ltr.					

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date.....

Inference:

Reviewed By
Manager QA
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

7.4 Test For Verification of Uniformity of Mixing at Minimum Speed of stirrer (15.0 Hz):

Trial No.:

Date of test		Capacity of vessel	
Name of equipment		Equipment Id no.	
Weight of sodium chloride		Location	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
After 05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
After 10	Top	Description	Lump free solution	
		pH	Below 8.0	
		Assay	Assay of active content should be within 0.882% W/V – 0.912% W/V	
	Bottom	Description	Lump free solution	
		pH	Below 8.0	
		Assay	Assay of active content should be within 0.882% W/V – 0.912% W/V	
	% RSD of Assay			≤ 2%
After 30	Top	Description	Lump free solution	
		pH	Below 8.0	
		Assay	Assay of active content should be within 0.882% W/V – 0.912% W/V	
	Bottom	Description	Lump free solution	
		pH	Below 8.0	
		Assay	Assay of active content should be within	



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
			0.882% W/V – 0.912% W/V	
		% RSD of Assay	≤ 2%	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

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

Reviewed By
Manager QA
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

7.5 Test For Verification of Uniformity of Mixing at Maximum Speed of stirrer (30.0 Hz):

Trial No.:

Date of test		Capacity of vessel	
Name of equipment		Equipment Id no.	
Weight of sodium chloride		Location	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
After 05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
After 10	Top	Description	Lump free solution	
		pH	Below 8.0	
		Assay	Assay of active content should be within 0.882% W/V – 0.912% W/V	
	Bottom	Description	Lump free solution	
		pH	Below 8.0	
		Assay	Assay of active content should be within 0.882% W/V – 0.912% W/V	
	% RSD of Assay			≤ 2%
After 30	Top	Description	Lump free solution	
		pH	Below 8.0	
		Assay	Assay of active content should be within 0.882% W/V – 0.912% W/V	
	Bottom	Description	Lump free solution	
		pH	Below 8.0	
		Assay	Assay of active content should be within	



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
			0.882% W/V – 0.912% W/V	
		% RSD of Assay	≤ 2%	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

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

Reviewed By
Manager QA
Sign/Date:

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

Tests or checks	Executed [Yes/No]	Remark
Equipment Volumetric Capacity (In Litres) Test		
Verification of Volume of Solution by assay of sodium chloride		
Test For Verification Of Uniformity Of Mixing		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

Reviewed By
Manager QA
Sign/Date:

9.0 DOCUMENTS ATTACHED:

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

10.0 NON COMPLIANCE:

.....



**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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

12.0 CHANGE CONTROL, IF ANY:

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

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

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

14.0 CONCLUSION :

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

15.0 RECOMMENDATION :

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



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

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



**PERFORMANCE QUALIFICATION REPORT
FOR
JACKETED MANUFACTURING
TANK**

PROTOCOL No.:

17.0 REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			