PERFORMANCE QUALIFICATION REPORT FOR JACKETED MANUFACTURING TANK SUGAR MELTING ROOM

EQUIPMENT ID. No.	
LOCATION	**Sugar Melting Room**
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	**NIL**

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

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 PHARMA DEVILS	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)			

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 Sugar Melting.
- 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	
Model	cGMP
Location of Installation	Sugar Melting 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.

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 Test For Verification Of Uniformity Of Mixing at Minimum Speed of stirrer:

Trial No.:01

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 5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		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 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	

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

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	% 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: ……

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

Trial No.:02

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 5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		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 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	

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

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
	% 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: ……

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

Trial No.:03

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 5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		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 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	

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

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
	% 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 Test For Verification of Uniformity of Mixing at Maximum Speed of stirrer:

Trial No.:01

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

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 5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		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 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		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:

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Reviewed By
Manager QA
Sign/Date: ……

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

Trial No.:02

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

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 5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		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 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	

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

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
	% 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: ……

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

Trial No.:03

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

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 5-7	
		Assay	Assay of active content should be within0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		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 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	
	Bottom	Description	Lump free solution	
		pH	Below 5-7	
		Assay	Assay of active content should be within 0.882% W/V – 0.912%W/V	

Sample interval (minute)	Sample location	Critical variables	Acceptance criteria	Observation
	% 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
Test For Verification Of Uniformity Of Mixing		

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.
- Training Record

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:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			