PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING VESSEL CAPACITY: 2000 LITER (FFS LINE)

EQUIPMENT ID. No.	
LOCATION	**MANUFACTURING AREA, FFS LINE**
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	**NIL**

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

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 report is limited for qualification of manufacturing vessel 2000 Ltr. (Make: Pharmatech Process Equipment) Installed in FFS Line.
- 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	SS Jacketed Manufacturing vessel
ID.Number	
Capacity	2000 lt.
Gross Capacity	2400 lt.
Manufacturer's Name	Pharmatech Process Equipment
S.No.	
Model	cGMP Model.
Supplier's Name	Pharmatech Process Equipment
Location of Installation	Manufacturing Area, FFS 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)	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: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

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
		Total volume to be 2000 liters	
		Working volume to be 2000 liters	
		Total volume to be 2000 liters	
		Working volume to be 2000 liters	
		Total volume to be 2000 liters	
		Working volume to be 2000 liters	

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 SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

7.2 Equipment Volumetric Capacity (In Liters) Test by chemical assay method

NAME OF EQUIPMENT		CAPACITY OF VESSEL	2000 Ltr.
MAKE		EQUIPMENT ID No.	
B.No. OF NACL		CONCENTRATION USED	

DATE OF TEST	VOLUME OF TANK	WEIGHT OF NACL	TEST PERFORMED	ACCEPTANCE CRITERIA	OBSERVATION
	200 Ltr.			Assay of NaCl should be between 0.882% W/V – 0.912%W/V	
	400 Ltr.				
	800 Ltr.				
	1200 Ltr.				
	1600 Ltr.				
	2000 Ltr.				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.3 Test for Verification of Uniformity of Mixing

DATE OF TEST		**CAPACITY OF VESSEL**	
NAME OF EQUIPMENT		**EQUIPMENT ID No.**	
WEIGHT OF SODIUM CHLORIDE		**TRIAL No.**	**01**

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	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	% RSD of Assay		≤ 2%	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

DATE OF TEST		**CAPACITY OF VESSEL**	
NAME OF EQUIPMENT		**EQUIPMENT ID NO.**	
WEIGHT OF SODIUM CHLORIDE		**TRIAL NO.**	**02**

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	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	% RSD of Assay		≤ 2%	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

DATE OF TEST		**CAPACITY OF VESSEL**	
NAME OF EQUIPMENT		**EQUIPMENT ID NO.**	
WEIGHT OF SODIUM CHLORIDE		**TRIAL NO.**	**03**

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	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	% RSD of Assay		≤ 2%	
After 30	Top	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (0.882 % w/v - 0.912 %. w/v	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (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: ……

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:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 DOCUMENTS ATTACHED:

- Test Report from QC lab
- Any other Relevant Documents.
- Calibration Certificate of test Instruments.

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
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
FFS	:	Form Fill Seal
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:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			