PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING VESSEL CAPACITY: 500 L

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

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

REPORT CONTENTS

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

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 500 L (Make – Bright Pharma Engineering Pvt. Ltd).
- 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, Authorization, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification. • 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	• Review of Performance Qualification Report. • Analytical Support (Chemical Testing/Analysis). • Post Approval of Performance Qualification Report after Execution.
Engineering	• Reviewing of qualification protocol 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.

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

5.0 EQUIPMENT DETAILS:

Equipment Name	Manufacturing vessel
Equipment	
Manufacturer's Name	
Model	cGMP Model
Supplier's Name	Bright Pharma Engineering Pvt. Ltd
Location of Installation	Manufacturing Room

EQUIPEMENT DESCRIPTION:

SS jacketed Mfg. tank and its components are designed to process pharmaceutical products in accordance with cGMP principles. Manufacturing Vessel is used for mixing of Pharmaceuticals product with bottom entry magnetic stirrer.

- Shell
- Jacket
- Spiral stiffner
- Insulation &cladding
- Stirrer
- SS panel
- Legs
- Rotating spray ball
- Compound gauge
- Sterile safety valve
- 0.2 micron plain vent filter
- Manual operated diapharagm valve
- Sparger tube

- Rupture disc
- Halogen lamp
- Temperature sensor with transmitter
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.
- Safety valve for jacket.
- PG For Jacket
- Auto Ball Valve
- Manual ball valve
- Auto steam trap unit
- Variable frequency drive
- Load cell
- Flexible hose for utility
- SS skid with castor wheel
- SS304 PLC panel

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 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	Document / SOP No	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) 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.	Executed and approved PQ Protocol				
5.	SOP for Preventive Maintenance of the manufacturing vessel				
6.	SOP for Operating, Cleaning of the manufacturing vessel				

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

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
	01	499.95 L to 500.50 L	
	02	499.95 L to 500.50 L	
	03	499.95 L to 500.50 L	

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

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

NAME OF EQUIPMENT		**CAPACITY OF VESSEL**	**500 L.**
MAKE		**EQUIPMENT ID NO.**	
B. No. OF NACL		**CONCENTRATION USED**	
ISSUANCE NO OF NACL			

DATE OF TEST	VOLUME OF TANK	WEIGHT OF NACL	TEST PERFORMED	ACCEPTANCE CRITERIA	OBSERVATION
	50 L				
	50 L				
	50 L				
	50 L				
	50 L				
	50 L				
	50 L				
	50 L				
	50 L				
	50 L				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

7.3 Test For Verification Of Uniformity Of Mixing

DATE OF TEST		**CAPACITY OF VESSEL**	
NAME OF EQUIPMENT		**EQUIPMENT ID No.**	
MAKE		**TRIAL No.**	**01**
B.No. /ISSUANCE No. OF NACL		**WEIGHT OF SODIUM CHLORIDE**	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
05	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
10	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	% RSD of Assay		≤ 2%	
30	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	% RSD of Assay		≤ 2%	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

DATE OF TEST		**CAPACITY OF VESSEL**	
NAME OF EQUIPMENT		**EQUIPMENT ID No.**	
MAKE		**TRIAL No.**	**02**
B.No. /ISSUANCE No. OF NACL		**WEIGHT OF SODIUM CHLORIDE**	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
05	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
10	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	% RSD of Assay		≤ 2%	
30	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	% RSD of Assay		≤ 2%	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

DATE OF TEST		**CAPACITY OF VESSEL**	
NAME OF EQUIPMENT		**EQUIPMENT ID No.**	
MAKE		**TRIAL No.**	**03**
B.No. /ISSUANCE No. OF NACL		**WEIGHT OF SODIUM CHLORIDE**	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
05	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
10	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	% RSD of Assay		≤ 2%	
30	Top	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	Bottom	Description	Lump free solution	
		pH	4.5 -7.0	
		Assay	Assay of active content should be within 90% to 100%.	
	% RSD of Assay		≤ 2%	

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

7.4 Test for efficiency of spray ball pattern

NAME OF EQUIPMENT		**CAPACITY OF VESSEL**	
MAKE		**EQUIPMENT ID No.**	

DATE OF TEST	ACCEPTANCE CRITERIA	OBSERVATION
	Spray pattern of water found all over 360 ° uniformly & all the surface of vessel internal should be free from riboflavin	

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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

PERFORMANCE QUALIFICATION REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

TESTS OR CHECKS	EXECUTED [Y/N]	REMARK	CHECKED BY (SIGN & DATE) QA
Equipment Volumetric Capacity (In Litres) Test			
Verification of Volume of Solution by assay of Sodium Chloride			
Test For Verification of Uniformity of Mixing			
Test For Efficiency of spray ball			

9.0 DOCUMENTS TO BE ATTACHED:

- Raw data from QC analysis
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED 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:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
ID	:	Inner Diameter
IQ	:	Installation Qualification
No.	:	Number
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
MFT	:	Manufacturing vessel
WHO	:	World Health Organization
PVT	:	Private
LTD.	:	Limited
ID.	:	Identification
RPQ	:	Report performance qualification
RSD	:	Relative standard deviation
%	:	Percentage
NaCl	:	Sodium Chloride

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)			