



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING VESSEL

EQUIPMENT ID. No.	
LOCATION	MANUFACTURING AREA
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL



**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

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PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)

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 (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 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 4000 Ltr. (Make: Pharmatech Process Equipment) Installed in Manufacturing Area.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.



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(4000 LITER)**

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, Review, Approved 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">• Approval 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.



**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

5.0 EQUIPMENT DETAILS:

Equipment Name	SS Jacketed Manufacturing vessel
ID.Number	
Capacity	4000 Ltr.
Gross Capacity	4805 Ltr.
Manufacturer's Name	Pharmatech Process Equipment
Sr.No	
Model	cGMP Model.
Supplier's Name	Pharmatech Process Equipment
Location of Installation	Manufacturing Area

3.0 SYSTEM DESCRIPTION:

Application: Jacketed (Limpeted) Manufacturing Vessel is used for Manufacturing of Pharmaceuticals product (LVP).

System Components

Jacketed (Limpeted) Manufacturing Vessel comprises of following parts.

- Shell

SS 316 L, Cylindrical, Vertical Shell, Top 10% Torispherical dish end & Bottom 10% Torispherical dish end welded to shell

Inside Surface Finish: Ra H 0.5 µm. Electro polish

- Limpet

SS 304, 4" NB x 3 mm Thick (Partial Limpet) @ 150 pitch Limpet coil.

- Insulation

38 mm Thick Armaflex insulation with 2 mm cladding on shell & 3 mm cladding on bottom cone. External surface finish: Ra H 0.9 µm. Mechanical polish

- Stirrer

Kweng make bottom entry magnetic stirrer

- Supports

3 Nos. of SS-304 Leg Support on load cell

- Facility Devices



**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

For vessel top

Spray ball

Sterile Safety valve

Compound gauge

Rupture disc

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for vent filter

Plain vent filter

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for vent filter condensate

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Halogen lamp

N₂ Sparger tube

Manual operated Diaphragm (PTFE with EPDM back up) valve for sparger

Manual operated Diaphragm (PTFE with EPDM back up) valve for CA/N₂ transfer

Manual operated Diaphragm (PTFE with EPDM back up) valve for WFI inlet

Manual operated Diaphragm (PTFE with EPDM back up) valve for CIP inlet at spray ball

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for SIP at spray ball

Pressure sensor with transmitter

Dip Stick

For vessel bottom

Manual operated flush bottom Diaphragm (PTFE) valve with manual operated sampling valve

For shell side

Resterilizable Diaphragm (Platinum cured silicon) Sample valve



**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for
SIP of sample valve

Manual operated Diaphragm (PTFE with EPDM back up) valve for sampling

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Temperature sensor with transmitter for vessel

For vessel limpet side

Pneumatic operated (on/off) Ball valve for steam inlet

Pneumatic operated (on/off) Ball valve for cooling water supply and return

Pneumatic operated (on/off) Ball valve for compressed air inlet

Safety valve for limpet

Pressure gauge for limpet

Pneumatic operated (on/off) Ball valve for limpet air vent

Auto steam trap unit

SS Braided hose pipe for utility

Other accessories

Load cell with IND 570 weight indicator

Variable Frequency drive

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for
SIP at drain

Manual operated diaphragm (PTFE with EPDM back up) valve for CIP drain

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Conductivity Sensor with Analyzer

Flexible hose for common drain header

Flexible hose, 1000 mm long (loose supply)

SS 304 fixed skid



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6.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

6.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S. NO.	DOCUMENT NAME	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY(QA) SIGN/DATE
1.	Executed and approved Design Qualification cum report			
2.	Executed and approved Installation Qualification cum report			
3.	Executed and approved Operational Qualification cum report			
4.	PQ Protocol approved			
5.	SOP for Operation & Cleaning of Manufacturing vessel			
6.	SOP for Preventive Maintenance Manufacturing vessel			



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6.2 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.

6.3 Calibration of Test /Measuring Instrument: Test Instrument Should be Calibrated.

NAME OF INSTRUMENT	INSTRUMENT ID No.	DATE OF CALIBRATION	DUE DATE	VERIFIED BY

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



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(4000 LITER)**

6.4 Biological Indicator Detail :

BI Detail	Observation	Verified By (QA) Sign/date
Name of Biological Indicator		
ATCC Code		
Lot Number		
Spore Population		
Z Value		
D Value		
Manufacturing Date		
Expiry Date		

Inference:

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Reviewed By:
(Manager QA)
(Sign & Date)



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PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 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
		(3999.7 to 4000.3)Ltr	
		(3999.7 to 4000.3)Ltr	
		(3999.7 to 4000.3)Ltr	

Checked By
(Production)
Sign/Date:

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

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



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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

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

NAME OF EQUIPMENT		CAPACITY OF VESSEL	
MAKE		EQUIPMENT ID NO.	
B.NO. OF NA CL		CONCENTRATION USED	

Date of test	Volume of tank	Weight of NaCl	Mixing time /RPM	Acceptance criteria	Qc result
	1000 Ltr.			Assay (0.882% W/V- .912% W/V)	
	1500 Ltr				
	2000 Ltr.				
	2500 Ltr.				
	3000 Ltr				
	3500 Ltr.				
	4000 Ltr.				

Checked By
(Production)
Sign/Date:

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

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



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7.3 Test For Verification Of Uniformity Of Mixing:

7.3.1 At Minimum RPM :

7.3.1.1 Cycle -01:

Date of test		Capacity of vessel	
Name of equipment		Equipment id no.	
Weight of sodium chloride		Stirrer RPM	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION Complies /Non Complies
05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
10	Top	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (98 % -.102%)	
% RSD of Assay			≤ 2%	
30	Top	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (98 % -.102%)	
% 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:



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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

7.3.1.2 Cycle -02:

Date of test		Capacity of vessel	
Name of equipment		Equipment id no.	
Weight of sodium chloride		Stirrer rpm	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
10	Top	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	% RSD of Assay			≤ 2%
30	Top	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5- 7.0	
		Assay	Assay (98 % -.102%)	
	% 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:



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PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)

7.3.1.3 Cycle -03:

Date of test		Capacity of vessel	
Name of equipment		Equipment id no.	
Weight of sodium chloride		Stirrer RPM	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION Complies /Non Complies
05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
10	Top	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (98 % -.102%)	
% RSD of Assay			≤ 2%	
30	Top	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5.0-7.0	
		Assay	Assay (98 % -.102%)	
	% 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:



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PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)

7.3.2 At Maximum RPM:

7.3.2.1 Cycle -01:

Date of test		Capacity of vessel	
Name of equipment		Equipment id no.	
Weight of sodium chloride		Stirrer RPM	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
10	Top	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	7.0	
		Assay	Assay (98 % -.102%)	
	% RSD of Assay			≤ 2%
30	Top	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	% 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:



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7.3.2.2 Cycle -02:

Date of test		Capacity of vessel	
Name of equipment		Equipment id no.	
Weight of sodium chloride		Stirrer RPM	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
10	Top	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	7.0	
		Assay	Assay (98 % -.102%)	
	% RSD of Assay			≤ 2%
30	Top	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	% 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:



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7.3.2.3 Cycle -03:

Date of test		Capacity of vessel	
Name of equipment		Equipment id no.	
Weight of sodium chloride		Stirrer rpm	

SAMPLE INTERVAL (MINUTE)	SAMPLE LOCATION	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
05	Top	Description	Lump free solution	
	Bottom	Description	Lump free solution	
10	Top	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	7.0	
		Assay	Assay (98 % -.102%)	
% RSD of Assay			≤ 2%	
30	Top	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
	Bottom	Description	Lump free solution	
		pH	5-7.0	
		Assay	Assay (98 % -.102%)	
% RSD of Assay			≤ 2%	

**Checked By
(Production)**
Sign/Date:

**Verified By
(Quality Assurance)**
Sign/Date.....

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Sign/Date:



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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

7.4 CIP : (Clean In Place):

7.4.1 Test for efficiency Of Washing Cycle For Manufacturing Tank with Product Line:

Date of Test		Equipment Name	
Block		Equipment ID	
Area		Equipment Make	

Parameter	Sample No.		
	5 % NaOH	10% NaOH	15% NaOH
pH			
Conductivity (Online)			
Conductivity (Offline)			

7.4.2 ACCEPTANCE CRITERIA:

Sr. NO.	Critical variables	Acceptance criteria
01	pH	5.0 to 7.0
02	Offline Conductivity	NMT 2.1 $\mu\text{s}/\text{cm}$
03	Online Conductivity	NMT 1.2 $\mu\text{s}/\text{cm}$

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Production
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Verified By
Quality Assurance
Sign/Date:

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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
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7.5 SIP (STERILIZATION IN PLACE):

7.5.1 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK WITH PRODUCT LINE:

Date of Test	
Test Instrument Name	
Make	
Model /Sr. No.	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

7.5.2 Parameter :

Parameter	Acceptance Criteria	Observation		
		Cycle-01	Cycle-02	Cycle-03
Cycle Start Date				
Purging Time	060 Second			
Sterilization Pressure	2.50 Bar			
Pressure Dead band	0.02 Bar			
Sterilization temperature	121.5 °C			
Heating ON Temperature	123.5 °C			
Heating OF Temperature	124 °C.0			
Sterilization Hold Time	30 Minute			
Sterilization Fail Temperature	119 .0 °C			
Overshoot Temperature	130 .0 °C			
Cooling Temperature	080 .0 °C			

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Sign/Date:

**Verified By
(Quality Assurance)**
Sign/Date:

Inference:

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



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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

7.5.3 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-1	Cycle -2	Cycle-3
	Internal	Internal	Internal
Cycle Start Date			
Cycle Start Time			
Sterilization start Time			
Sterilization end Time			
Cycle End Time			
Cycle End Date			
Total Hold time			

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

7.5.4 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-1	Cycle -2	Cycle-3
	External	External	External
Cycle Start Date			
Cycle Start Time			
Sterilization start Time			
Sterilization end Time			
Cycle End Time			
Cycle End Date			

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(Manager QA)
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

7.5.5 F₀ CALCULATION

(a) (a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z}$$

F₀ =

Where,

dt : Time interval between successive temperature measurements (in min).

T : Observed temperature at that particular time (as per the actual temperatures recorded)

Z = change in the heat resistance of *Geobacillus stearothermophilus* spores as temperature is changed (as mentioned in COA).

(b) F₀ Value for Biological Indicators:

The biological F₀ value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B)$$

F₀ =

Where,

D₁₂₁ : D value of the biological indicator at 121⁰C

A : Experimental Biological indicator concentration or spore population

B : Desired level of sterility (SAL- 10⁻⁶)

(c) Desired Spore log reduction:

Calculate the desired reduction in spore population by using the formula-

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}}$$

SLR_{desired} =

Where,

A : Experimental population of Biological Indicator

SLR_{desired} : Desired level of sterility (10⁻⁶)

(d) Actual Spore log reduction

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121}$$

SLR_{Actual} =

Where,

F₀ : Minimum Calculated F₀ value

D₁₂₁ : D value of the Biological Indicator at 121⁰C



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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

S.No.	Name of Test or Check	Execution (Yes/No.)	Remark
1.	Calibration Status of Test Instrument		
2.	Equipment Volumetric Capacity (in liters) Test		
3.	Equipment Volumetric Capacity (in liters) Test by chemical method		
4.	Verification of Uniformity of Solution		
5.	CIP		
6.	Heat Distribution Study (SIP)		

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

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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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

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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**PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL
(4000 LITER)**

16.0 ABBREVIATIONS:

%	:	Percentage
cGMP	:	Current Good Manufacturing Practices
ID.	:	Identification
MFT	:	Manufacturing vessel
Nacl	:	Sodium Chloride
No.	:	Number
PPQ	:	Performance Qualification Protocol
RPQ	:	performance qualification Report
RSD	:	Relative standard deviation
SIP	:	Sterilization in Place
CIP	:	Clean in Place
SOP	:	Standard Operating Procedure



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)

17.0 REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			