PERFORMANCE QUALIFICATION

REPORT

FOR

HOLDING VESSEL

EFFECTIVE DATE OF REPORT	
EQUIPMENT ID. No.	
LOCATION	Filtration Room of Ampoule
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL

REPORT CONTENTS

1.0 REPORT PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
MANAGER/EXECUTIVE (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING			
HEAD (QUALITY CONTROL)			

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 Holding vessel 1000 Ltr. (Make Pharmatech.
- Process Equipment) Installed in Filtration Room of Ampoule.
- 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, 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	• Reviewing of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity.
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.

5.0 EQUIPMENT DETAILS:

Equipment Name	1000 Ltrs. Holding Vessel
ID. Number	
Manufacturer's Name	Pharmatech
Location of Installation	Filtration Room of Ampoule
Capacity	1000 Ltrs. Working

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	Document / Sop No.	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 Holding vessel				
6.	SOP for Preventive Maintenance of Holding vessel				

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 Instrument: Test Instrument Should be Calibrated.

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

Inference:

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Reviewed By
(Quality Assurance)
Sign/Date: ……

7.0 TESTS AND CHECKS :

7.1 Equipment Volumetric Capacity (In Liters) Test by water:

NAME OF EQUIPMENT	Holding Vessel	**CAPACITY OF VESSEL**	1000 Liter

DATE OF TEST	TRIAL NO.	ACCEPTANCE CRITERIA	OBSERVATION
		(999.7 to 1000.3)Ltr	
		(999.7 to 1000.3)Ltr	
		(999.7 to 1000.3)Ltr	

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Quality Assurance)
Sign/Date: ……

7.2 Riboflavin Challenge Test (CIP Study):

Test for efficiency Of Washing Cycle for Holding tank:

Date of Test		**Equipment Name**	
Block		**Equipment ID**	
Area		**Equipment Make**	

Parameter	Results
pH	
Conductivity (On line)	
Conductivity (Off line)	

- **ACCEPTANCE CRITERIA:**

S.No.	Critical variables	Acceptance criteria
1	pH	5.0 to 7.0
2	Offline Conductivity	NMT 2.1 µs/cm
3	Online Conductivity	NMT 1.3 µs/cm

Checked By
Production
Sign/Date: ……..

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

Inference

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Reviewed By
(Quality Assurance)
Sign/Date: ……

7.3 SIP (STERILIZATION IN PLACE):

7.3.1 HEAT DISTRIBUTION STUDY FOR HOLDING TANK:

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

7.3.2 Parameter :

Parameter	Acceptance Criteria		Observation		
			Cycle-01	Cycle-02	Cycle-03
Cycle Start Date					
Set leak test Pressure (PS1)	1.50	BAR			
Leak test pressure stabilize time	60	SEC			
Leak Rate NMT	0.30	BAR			
Pressure Hold time	5	MIN			
Sterilization temperature	122.0	℃			
Sterilization stabilizing time	120	SEC			
Sterilization Hold Time	30	MIN			
Sterilization Fail Temperature	120.9	℃			
Cooling High pressure	1.50	BAR			
Cooling Low pressure	1.20	BAR			
Print Interval	60	SEC			

Checked By
(Production)
Sign/Date: ……..

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

Inference:

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Reviewed By
(Quality Assurance)
Sign/Date: ……

7.3.3 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-1 Internal	Cycle -2 Internal	Cycle-3 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: ……..
Inference:

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

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Reviewed By

Quality Assurance)

Sign/Date: ……..

7.3.4 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			
Cold Spot Location			
Cold Spot Sensor No.			

Checked By
(Production)
Sign/Date: ……..

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

Inference:

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Reviewed By
(Quality Assurance)
Sign/Date: ……..

7.3.5 Fo CALCULATION

(a) Numerical F_0 Value:

Calculate numerical F_0 value for below given formula.

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

$F_0 =$

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) F_0 Value for Biological Indicators:

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

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

$F_0 =$

Where,

D_{121} : D value of the biological indicator at 121^0C
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-

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

$SLR_{desired} =$

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

$SLR_{Actual} = F_0 / D_{121}$_____

$SLR_{Actual} =$

Where,

F_0 : Minimum Calculated $F_{0\ value}$

D_{121} : D value of the Biological Indicator at 121^0C

7.3.6 OBSERVATIONS:

Cycle : 01

Probe No	Sterilizing Temperature (°c)		F_o Value		Spore Log Reduction		Biological Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual	

Checked By
(Production)
Sign/Date: ……..

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

Inference:

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Reviewed By

(Quality Assurance)
Sign/Date: ……

	PERFORMANCE QUALIFICATION REPORT FOR HOLDING VESSEL (1000 LITER)	PROTOCOL No.:
		REVISION No.: 00
		REPORT No.:
		REVESION No.: 00
		PAGE No: 14 of 20

Cycle : 02

Probe No	Sterilizing Temperature (°c)		F_o Value		Spore Log Reduction		Biological Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual	

Checked By
(Production
Sign/Date: ……..
Inference:

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

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Reviewed By

(Quality Assurance)
Sign/Date: ……

Cycle: 03

Probe No	Sterilizing Temperature (°c)		F_o Value		Spore Log Reduction		Biological Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual	

Checked By
(Production
Sign/Date: ……..

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

Inference:

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Reviewed By
(Quality Assurance)
Sign/Date: ……

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

TESTS OR CHECKS	EXECUTED [YES/NO]	REMARK
Calibration Status of Test Instrument		
Heat Distribution Study (SIP)		
Equipment Volumetric Capacity (In Litres) Test		
Riboflavin Challenge Test (CIP Test)		

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Quality Assurance)
Sign/Date: ……

9.0 DOCUMENTS ATTACHED:

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

10.0 NON COMPLIANCE, IF ANY:

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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
ID.	:	Identification
HV	:	Holding vessel
Nacl	:	Sodium Chloride
No.	:	Number
PQ	:	Performance Qualification Protocol

RSD : Relative standard deviation

SIP : Sterilization in Place

SOP : Standard Operating Procedure

A1 : Ampoule-1

17.0 REVISION HISTORY:

Revision No.	Change Control No.	Detail of Changes	Reason for Change	Effective Date	Updated By
00	NA	NA	New Protocol		

18.0 REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			