PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

EQUIPMENT ID No.	
LOCATION	**LOADING AREAK**
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	**NIL**

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

REPORT CONTENTS

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

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 SUPER HEATED WATER SPRAY STERILIZER

2.0 OBJECTIVE:

- To compile the Validation report carried out as per Protocol for Super Heated Water Spray Sterilizer installed in the LVP Line Loading Area.

3.0 SCOPE:

- The Report covers all aspects of Performance Qualification for the Super Heated Water Spray Sterilizer installed in the LVP Line Loading Area.

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4.0 RESPONSIBILITY:

- The Validation Group, comprising of a representative from each of the following Departments, shall be responsible for the overall compliance of this Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Control	• Preparation of Reports and submission to Quality Assurance Department. • To conduct Validation activity as per the Approved Protocol. • To provide analytical support for validation activity.
Quality Assurance	• Review of Performance Qualification Report. • To compile and approval of report. • To monitor all Validation Activities and ensure the Validation is carried out as per the Protocol. • To review Report for completeness and Technical Accuracy.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance qualification Activity.
Engineering	• Review of Performance Qualification Report. • To co-ordinate and support Validation Activity. • Responsible for Trouble shooting during execution (If Occurs).

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

5.0 EQUIPMENT DETAILS:

Equipment Name	**Super Heated Water Spray Sterilizer**
Equipment ID. No.	
Size	**1750 DIA X 4500 LG mm**
Chamber volume	**10800 Liters**
Manufacturer's Name	**M/s Machine Fabrik**
Supplier's Name	**M/s Machine Fabrik**
Place of Installation	**LVP Line Loading Area**

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 Training Record of Validation Team:

- All the persons involved in the execution of qualification activity including the persons of outside agencies must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

  Verify the training records and attached

6.2 Calibration of Test Instruments: Calibration of all the instruments used for qualification should be mentioned along with Calibration Certificates.

S. No.	Name of Test Instrument	Date of Last Calibration	Next Due on	Status	Availability of Calibration Certificate	Verified By (QA) Sign/Date

Inference:

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

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

6.3 Biological Indicator Detail :

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

Inference:

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

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

6.0 TESTS & CHECKS:

6.1 EMPTY CHAMBER HEAT DISTRIBUTION STUDY

Name of Cycle	Heat Distribution Study (For Empty Chamber)

6.1.1 OBSERVATION OF CYCLE SET PARAMETER

Parameters	Set Value	Cycle Observed Value		
		Cycle -01	Cycle-02	Cycle-03
Cycle Start Date				
Cycle Start Time				
Add water in	30 Sec.			
Initial H/E Exhaust	03 min			
Set Point 1	95.0^{0}C			
Set Point 2	100.0^{0}C			
Set Point 3	105.0^{0}C			
Rate 1	5.0^{0}C			
Rate 2	4.0^{0}C			
Rate 3	2.0^{0}C			
Sterilization Temperature	108.0 ^{0}C			
Sterilization Time	60 min.			
Control Band	0.2 ^{0}C			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

Parameters	Set Value	Cycle Observed Value		
		Cycle -01	Cycle-02	Cycle-03
Overshoot Temperature	110.0 ^{0}C			
Sterilization Stop Temperature	107.5 ^{0}C			
Sterilization Reset Temperature	107.0 ^{0}C			
H/E Exhaust Delay Time	3 min.			
H/E Cooling Exhaust	3 min.			
Slow Cooling & Temperature	85 ^{0}C			
Cooling End Temperature	50 ^{0}C			
H/E Drain Time	5 min.			
Process End Pressure	0.030 Bar			
Cycle End Date &Time				

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.1.2 SUMMARY DETAIL OF STERILIZATION PROCESS

S. No.	Critical variables	CYCLE					
		Internal			External		
		Cycle-01	Cycle-02	Cycle-03	Cycle-01	Cycle-02	Cycle-03
01	Date						
02	Set sterilization temperature						
03	Time process start						
04	Sterilization start Time						
05	Sterilization End Time						
06	Cycle end time						
07	Location of sensor						
08	Sensor no at Cold point						
09	Equilibrium Time						

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.4 HEAT PENETRATION STUDY MINIMUM LAOD

Name of Cycle	Heat Penetration Study

6.4.1 OBSERVATION OF CYCLE SET PARAMETER

Parameters	Set Value	Cycle Observed Value		
		Cycle-01	Cycle-02	Cycle-03
Cycle Start Date				
Cycle Start Time				
Add water in	30 Sec.			
Initial H/E Exhaust	03 min			
Set Point 1	95.0^0C			
Set Point 2	100.0^0C			
Set Point 3	105.0^0C			
Rate 1	5.0^0C			
Rate 2	4.0^0C			
Rate 3	2.0^0C			
Sterilization Temperature	108.0 ^{0}C			
Sterilization Time	60 min.			
Control Band	0.2 ^{0}C			
Overshoot Temperature	110.0 ^{0}C			
Sterilization Stop Temperature	107.5 ^{0}C			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

Parameters	Set Value	Cycle Observed Value		
		Cycle-01	Cycle-02	Cycle-03
Sterilization Reset Temperature	107.0 ^{0}C			
H/E Exhaust Delay Time	3 min.			
H/E Cooling Exhaust	3 min.			
Slow Cooling & Temperature	85 ^{0}C			
Cooling End Temperature	50 ^{0}C			
H/E Drain Time	5 min.			
Process End Pressure	0.030 Bar			
Cycle End Date & Time				

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.4.2 SUMMARY DETAIL OF STERILIZATION PROCESS

Sr. NO.	Critical variables	CYCLE					
		Internal			External		
		Cycle-01	Cycle-02	Cycle-03	Cycle-01	Cycle-02	Cycle-03
01	Date						
02	Set sterilization temperature						
03	Time process start						
04	Sterilization start Time						
05	Sterilization End Time						
06	Cycle end time						
07	Location of sensor						
08	Sensor no at Cold point						
09	Equilibrium Time						

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.4.3 OBSERVATION REPORT OF BIOLOGICAL INDICATOR & CHEMICAL INDICATOR.

Status of Biological Indicator					
Cycle-I		Cycle-II		Cycle-III	
Sr. No.	Observation	Sr. No.	Observation	Sr. No.	Observation
01		01		01	
02		02		02	
03		03		03	
04		04		04	
05		05		05	

Status of Chemical Indicator					
Cycle-I		Cycle-II		Cycle-III	
Sr. No.	Observation	Sr. No.	Observation	Sr. No.	Observation
01		01		01	

Verified By
(Quality Assurance)
Sign/Date……

6.4.4 Fo CALCULATION

(a) Numerical F_0 Value:

The actual observations obtained during the heat penetration study at different temperature sensing locations are compiled in the table and the observed temperature shall be subjected for calculation of F_0 values at that particular location. The lethality factor calculations are done by using the following formula and the computed (during the sterilization period) are given in the following table.

$F_0 = dt \sum 10^{(T-121.1)/Z}$ _____ (a)

$F_0 = dt \sum$ (Sum of lethality factors)

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 *Bacilus Subtilis* spores as temperature is changed (10^0C or 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) …… (b)
F_0 = ...(log.....-log.....)
F_0 =
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- 10^0)

(c) Desired Spore log reduction:

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

$SLR_{desired}$ = log A- log $SAL_{desired}$ ----------(c)
$SLR_{desired}$ =

$SLR_{desired}$ =

Where, A: Experimental population of Biological Indicator
SAL: Desired level of Sterility (10^0)

(d) Actual Spore log reduction:

Calculate actual reduction in spore population by using the formula-

$SLR_{Actual} = F_0 / D_{121}$---------- (d)

Where,

F_0 : Minimum Calculated F_0 value
D_{121} : D value of the Biological Indicator at 121^0C

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

(E) Sterility Assurance Level :

= SLR_{Actual} - Initial population of BI

6.4.5 F_O CALCULATION FOR CYCLE 01:

Sensor No.	Sterilizing Temperature (°C)		F0 Value		Spore Log Reduction		SAL	
	Maximum	Minimum	Numerical	BI	Desired	Actual	Desired	Actual

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.4.6 F_O CALCULATION FOR CYCLE 02:

Sensor No.	Sterilizing Temperature (°C)		F0 Value		Spore Log Reduction		SAL	
	Maximum	Minimum	Numerical	BI	Desired	Actual	Desired	Actual

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.4.7 F_O CALCULATION FOR CYCLE 03:

Sensor No.	Sterilizing Temperature (°C)		F0 Value		Spore Log Reduction		SAL	
	Maximum	Minimum	Numerical	BI	Desired	Actual	Desired	Actual

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.5 HEAT PENETRATION STUDY MAXIMUM LAOD

Name of Cycle	Heat Penetration Study

6.5.1 OBSERVATION OF CYCLE SET PARAMETER

Parameters	Set Value	Cycle Observed Value		
		Cycle-01	Cycle-02	Cycle-03
Cycle Start Date				
Cycle Start Time				
Add water in	30 Sec.			
Initial H/E Exhaust	03 min			
Set Point 1	95.0^{0}C			
Set Point 2	100.0^{0}C			
Set Point 3	105.0^{0}C			
Rate 1	5.0^{0}C			
Rate 2	4.0^{0}C			
Rate 3	2.0^{0}C			
Sterilization Temperature	108.0 ^{0}C			
Sterilization Time	60 min.			
Control Band	0.2 ^{0}C			
Overshoot Temperature	110.0 ^{0}C			
Sterilization Stop Temperature	107.5 ^{0}C			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

Parameters	Set Value	Cycle Observed Value		
		Cycle-01	Cycle-02	Cycle-03
Sterilization Reset Temperature	107.0 ^{0}C			
H/E Exhaust Delay Time	3 min.			
H/E Cooling Exhaust	3 min.			
Slow Cooling & Temperature	85 ^{0}C			
Cooling End Temperature	50 ^{0}C			
H/E Drain Time	5 min.			
Process End Pressure	0.030 Bar			
Cycle End Date & Time				

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.5.2 SUMMARY DETAIL OF STERILIZATION PROCESS

Sr. NO.	Critical variables	CYCLE					
		Internal			External		
		Cycle-01	Cycle-02	Cycle-03	Cycle-01	Cycle-02	Cycle-03
01	Date						
02	Set sterilization temperature						
03	Time process start						
04	Sterilization start Time						
05	Sterilization End Time						
06	Cycle end time						
07	Location of sensor						
08	Sensor no at Cold point						
09	Equilibrium Time						

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.5.3 OBSERVATION REPORT OF BIOLOGICAL INDICATOR & CHEMICAL INDICATOR.

Status of Biological Indicator					
Cycle-I		Cycle-II		Cycle-III	
Sr. No.	Observation	Sr. No.	Observation	Sr. No.	Observation
01		01		01	
02		02		02	
03		03		03	
04		04		04	
05		05		05	
06		06		06	
07		07		07	
08		08		08	
09		09		09	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	

Status of Chemical Indicator					
Cycle-I		Cycle-II		Cycle-III	
Sr. No.	Observation	Sr. No.	Observation	Sr. No.	Observation
01		01		01	
02		02		02	
03		03		03	
04		04		04	

Verified By
(Quality Assurance)
Sign/Date……

6.5.4 Fo CALCULATION

(a) Numerical F_0 Value:

The actual observations obtained during the heat penetration study at different temperature sensing locations are compiled in the table and the observed temperature shall be subjected for calculation of F_0 values at that particular location. The lethality factor calculations are done by using the following formula and the computed (during the sterilization period) are given in the following table.

$F_0 = dt \sum 10^{(T-121.1)/Z}$ _____ (a)

$F_0 = dt \sum$ (Sum of lethality factors)

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 *Bacilus Subtilis* spores as temperature is changed (10^0C or 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) …… (b)
F_0 = ...(log.....-log.....)
F_0 =
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- 10^0)

(c) Desired Spore log reduction:

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

$SLR_{desired}$ = log A- log $SAL_{desired}$ ----------(c)
$SLR_{desired}$ =

$SLR_{desired}$ =

Where, A: Experimental population of Biological Indicator
SAL: Desired level of Sterility (10^0)

(d) Actual Spore log reduction:

Calculate actual reduction in spore population by using the formula-

$SLR_{Actual} = F_0 / D_{121}$---------- (d)

Where,

F_0 : Minimum Calculated F_0 value
D_{121} : D value of the Biological Indicator at 121^0C

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

(F) Sterility Assurance Level :

= SLR_{Actual} - Initial population of BI

6.5.5 F_O CALCULATION FOR CYCLE 01:

Sensor No.	Sterilizing Temperature (°C)		F0 Value		Spore Log Reduction		SAL	
	Maximum	Minimum	Numerical	BI	Desired	Actual	Desired	Actual

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.5.6 F_O CALCULATION FOR CYCLE 02:

Sensor No.	Sterilizing Temperature (°C)		F0 Value		Spore Log Reduction		SAL	
	Maximum	Minimum	Numerical	BI	Desired	Actual	Desired	Actual

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.5.7 F_O CALCULATION FOR CYCLE 03:

Sensor No.	Sterilizing Temperature (°C)		F0 Value		Spore Log Reduction		SAL	
	Maximum	Minimum	Numerical	BI	Desired	Actual	Desired	Actual

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.6 BOTTLES LEAK TEST CHALLENGE STUDY MINIMUM LOAD

BOTTLES LEAK TEST DETAILS	
Equipment Name	
Equipment Make	
Equipment Location	
Equipment ID No.	

Name of Cycle	Bottles Leak Test Challenge			
Date				
Parameters	**Set Value**	**Cycle Observed Value**		
		Cycle-I	**Cycle-II**	**Cycle-III**
Cycle Started Date				
Cycle Started Time				
Cycle Completed Date				
Cycle Completed Time				
Vacuum	**-0.700 Bar**			
Vacuum Band	**0.050 Bar**			
Vacuum hold time	**10 Min.**			
Pressure	**-0.200 Bar**			
No of pulses	**3 Nos.**			
Process end pressure	**-0.030 Bar**			
Actual Leakage				

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.6.1 OBSERVATIONS OF BOTTLES LEAK TEST

Sr. No.	Para-meter	CYCLE											
		Cycle-01				Cycle-02				Cycle-03			
		Trolley -I	Trolley -II	Trolley -III	Trolley -IV	Trolley -I	Trolley -II	Trolley -III	Trolley -IV	Trolley -I	Trolley -II	Trolley -III	Trolley -IV
01	No. of Leak Bottles												
02	Status												
03	Checked By												
04	Verified By												
05	Remark												

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 SUPER HEATED WATER SPRAY STERILIZER

6.7 BOTTLES LEAK TEST CHALLENGE STUDY MAXIMUM LOAD

BOTTLES LEAK TEST DETAILS	
Equipment Name	
Equipment Make	
Equipment Location	
Equipment ID No.	

Name of Cycle	Bottles Leak Test Challenge			
Date				
Parameters	**Set Value**	**Cycle Observed Value**		
		Cycle-I	**Cycle-II**	**Cycle-III**
Cycle Started Date				
Cycle Started Time				
Cycle Completed Date				
Cycle Completed Time				
Vacuum	**-0.700 Bar**			
Vacuum Band	**0.050 Bar**			
Vacuum hold time	**10 Min.**			
Pressure	**-0.200 Bar**			
No of pulses	**3 Nos.**			
Process end pressure	**-0.030 Bar**			
Actual Leakage				

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 FOR SUPER HEATED WATER SPRAY STERILIZER

6.7.1 OBSERVATIONS OF BOTTLES LEAK TEST

Sr. No.	Critical variables	CYCLE											
		Cycle-01				Cycle-02				Cycle-03			
		Trolley -I	Trolley -II	Trolley -III	Trolley -IV	Trolley -I	Trolley -II	Trolley -III	Trolley -IV	Trolley -I	Trolley -II	Trolley -III	Trolley -IV
01	No. of Leak Bottles												
02	Status												
03	Checked By												
04	Verified By												
05	Remark												

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 SUPER HEATED WATER SPRAY STERILIZER

7.0 CHECKLIST OF ALL TESTS AND CHECKS:

TESTS OR CHECKS	EXECUTED [Y/N]	CHECKED BY (SIGN & DATE) QA	COMMENT
Heat Distribution Study			
Minimum Loaded Chamber Heat Penetration Studies with Biological Indicator Placement For 100 ml LDPE bottles. **(3960 Bottles)**			
Maximum Loaded Chamber Heat Penetration Studies with Biological Indicator Placement For 100 ml LDPE bottles. **(15840 Bottles)**			
Bottle Leakage Test (Minimum Load) **(3960 Bottles)**			
Bottle Leakage Test (Maximum Load) **(15840 Bottles)**			

Compiled By
(Quality Assurance)
(Sign & Date)……

Inference:

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

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.0 DOCUMENTS ATTACHED:

- Raw data of Microbiological Analysis
- Calibration Certificates for Data Logger & Temperature Sensor.
- COA of Biological Indicator.
- Data Logger Printouts.
- Super Heated Water Spray Sterilizer PLC Printouts.

9.0 NON COMPLIANCE:

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10.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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11.0 CHANGE CONTROL, IF ANY:

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PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

12.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY) :

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13.0 CONCLUSION:

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14.0 RECOMMENDATION:

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15.0 ABBREVIATIONS:

QA	:	Quality Assurance
QC	:	Quality Control
No.	:	Number
Ltd.	:	Limited
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
CQA	:	Corporate Quality Assurance
GMP	:	Good Manufacturing Practices
cGMP		Current Good Manufacturing Practices
WHO	:	World Health Organization
SOP	:	Standard Operating Procedure

PERFORMANCE QUALIFICATION REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

16.0 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)			