

PROTOCOL No.:

EQUIPMENT ID. No.	
LOCATION	Vial Washing and De-Pyrogenation
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL



PROTOCOL No.:

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PERFORMANCE QUALIFICATION REPORT FOR

PROTOCOL No.:

STERILIZINF & DEPYROGENATING TUNNEL

1.0	PRE –	APPRO	VAL:
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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)			



PROTOCOL No.:

2.0 OBJECTIVE:

The objective of this Report is to establish that Sterilization & Depyrogenating tunnel meets the following criteria:

The Sterilization and Depyrogenating tunnel performs as per the pre-defined parameters and/or quality attributes.

3.0 SCOPE:

- The Report covers all aspects of Performance Qualification for the Sterilizing and Depyrogenating
 Tunnel (Make Fabtech Technologies Pvt. Ltd.) installed in the Vial Washing & Depyrogenating
 of
- 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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4.0 **RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the verification and evaluation of performed tests results.

DEPARTMENTS		RESPONSIBILITIES		
Quality Assurance	Initiation, Approval Compilation and Authorization of the Performance			
	(Qualification.		
	• (Co-ordination with Quality Control, Production and Engineering to		
	C	carryout Performance Qualification Activity.		
	• 1	Monitoring of Performance Qualification.		
Production	• I	Review of Report.		
	• 7	Γο co-ordinate and support Performance Qualification Activity.		
Quality Control	• I	Review of Report.		
	• A	Analytical Support (Microbiological Testing / Analysis)		
Engineering	• I	Reviewing of qualification Report for correctness, completeness and		
	1	technical excellence		
	• I	Responsible for trouble shooting (if occurred during execution).		
	• 1	Maintenance & preventive maintenance as per schedule.		



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5.0 EQUIPMENT DETAILS:

Equipment Name	Sterilizing and De-pyrogenating Tunnel
Equipment ID.	
Manufacturer's Name	Fabtech Technologies Int. Pvt. Ltd.
Supplier's Name	cGMP Model
Model	Fabtech Technologies Int. Pvt. Ltd.
Location of Installation	Vial Washing and Depyrogenating Tunnel

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.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Sterilizing and De-pyrogenating Tunnel.
- SOP for Preventive Maintenance Sterilizing and De-pyrogenating Tunnel.



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7.0 TESTS AND CHECKS:

7.1 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				
	document				
2.	Executed and approved				
	Installation Qualification				
	document				
3.	Executed and approved				
	Operational Qualification				
	document				
4.	PQ Protocol approved				
5.	SOP for Operation &				
	Cleaning of Sterilizing and				
	De-pyrogenating Tunnel				
6.	SOP for Preventive				
	Maintenance Sterilizing				
	and De-pyrogenating				
	Tunnel				
	ked By			erified By	
	uction)		•	Quality Assuran	•
Sign/	Date:		ì	Sign/Date:	•••••
Infer	ence:				
			ŀ	Reviewed By Manager QA)	
				Sign/Date:	



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7.2 Air velocity measurement:

Date of Test	
Name of Instrument Used for Testing	Digital Anemometer
Calibrated on	
Calibration due on	

HEDA			Vel	ocity [FF	PM]		Average	Dono Bri
HEPA Filter No.	Location	V1	V2	V3	V4	V5	Velocity [FPM]	Done By Sign & Date
1.	Drying Zone							
2.	Sterilizing Zone							
3.	Cooling & Stabilizing Zone							

Acceptance Criteria

The Average measured clean air velocity at downstream of filter face.

- **Drying Zone:** 120 ft. / min. ± 20% (96 to 144 ft. / min.)
- **Sterilizing Zone:** 150 ft. / min. \pm 20% (120 to 180 ft. / min.)
- **Cooling & Stabilizing Zone:** 120 ft. / min. ± 20% (96 to 144 ft. / min.)

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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7.3 Filter Integrity Test (PAO Test) Of HEPA Filter:

		, ·		
Date of '	Test			
Name of	Instrument	Aerosol Photometer		
Calibrate	ed on			
Calibrati	ion due on			
S.No.	HEPA Filter Location	Filter Size	Observed Downstream Concentration	Done By Sign & Date
1.	Drying Zone	610×460×50		
2.	Sterilization Zone	610×460×150		
3.	Sterilization Zone	610×460×150		
4.	Cooling Zone	610×460×50		
5.	Cooling Zone	610×460×50		
Acceptar	nce Criteria:			L
The PAO	Penetration Leak Through H	EPA Filters Should No	t Be Greater Than 0.03% of The Up	ostream PAO
Concentra	ation			
Checked (Product Sign/Dat			Verified By (Quality Assurance) Sign/Date:	
Inference	e:			
			Reviewed By (Manager QA)	
			Sign/Date:	



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7.4	Non –	viable	particle	count	test:
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Date of Test	
Name of Instrument used for Testing	
Calibrated on	
Calibration due on	

HEPA			Particle	Partic	le Count Lo	Average	Done By	
Filter No.	Filter Location	Location	Size	Cycle 1	Cycle 2	Cycle 3	nverage	Sign & Date
1.	Drying	L1	≥0.5 µ					
1.	Zone		≥5.0 μ					
		L2	≥0.5 µ					
2.	Sterilizing	1.2	≥5.0 µ					
2.	Zone	L3	≥0.5 µ					
			≥5.0 µ					
		L4	≥0.5 µ					
3.	Cooling &	L4	≥5.0 µ					
	Stabilizing Zone	_	≥0.5 µ					
			≥5.0 µ					

Checke (Produc	•				Verified (Ouality	By Assurance)	
	ite:					e :	,
Inferen	ce:						
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					(Manage Sign/Dat	er QA) te:	



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7.5 Recovery Test:

Instrument Name	
Make	
Instrument Id.	
Model/Type	
Calibration Date	
Calibration Due Date	
Area	Vial Washing & Sterilization

Particulate Counts Readings								
	AHU "ON"		AHU "OFF"					
Time	≥ 0.5	≥5.0	Time	≥0.5	≥5.0			



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Name of Area	Recovery Time of Each Location (Acceptance Criteria: NMT 20 Minutes)									
	Location No.	Area Recovery Time	Area Uncontrolled Time							
Vial Washing & Sterilization	First Floor, I-Block									
Average Re	covery Time									

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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7.6	Differential Pressure Reco	rd:					
Magnel	nelic Gauge ID. No.						
Date of	Calibration						
Calibra	tion due date						
Accepta	nnce Criteria						
				Obse	ervation		
Date	Differential Pressure	M	orning	Aft	ernoon	E	vening
		Time	Pressure (Pa)	Time	Pressure (Pa)	Time	Pressure (Pa)
Checke (Produc Sign/Da					Verifie (Qualit Sign/D	y Assuran	ace)
Inferen	ce:						
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7.7 Test Instrument Details To Be Used For Pre-Calibration

Test Inst	rument I	Name											
Sensors ty	ype & Qt	ty.											
Calibratio	on done	Date											
Model No)												
Make													
Calibratio	on due D	ate											
Pre- Calib	oration o	of Senso	rs at 0°	C									
Date	Time	СН-1	СН-2	СН-3	CH-4	СН-5	СН-6	СН-7	СН-8	СН-9	СН-10	CH-11	CH-12
Pre- Calib	oration o	of Senso	rs at 25	0°C									
Pre- Calib	oration o	of Senso	r at 300)°C									



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Pre- Calib	oration o	of Senso	r at 35()°C									
			T	T	T	T			T	T			
Acceptane	ce criter	ia:											
Temperatu			fluctua	ting mo	re than :	± 1°C fr	om the	mean of	temper	atures sl	nown by	the cal	ibrated
thermome	ter during	g the dat	ta-loggi	ng perio	d.								
Checked By (Production) (Quality Assurance) Sign/Date: Sign/Date:													
Inference	•												
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7.8 Test Instrument Details To Be Used For Post Calibration

Test In	strument]	Name											
Sensors	type & Q	ty.											
Calibra	tion done	Date											
Model N	No												
Make													
Calibra	tion due D	ate											
D4 C-1	!!L 4!	£ C	4 00										
Post Cal	libration o	or Senso	rs at U										
Date	Time	CH-1	CH-2	СН-3	СН-	4 CH-5	CH-6	CH-7	СН-8	СН-9	CH-10	CH-11	CH-12
.		0.0		100 G									
Post Ca	libration (of Senso	ors at 25	0°C									
Date	Time	CH-1	CH-2	СН-3	СН-4	CH-5	СН-6	СН-7	СН-8	СН-9	CH-10	CH-11	CH-12
Post Ca	libration (of Senso	r at 300)°C	l	1		I			I		
Date	Time	СН-1	СН-2	СН-3	СН-4	CH-5	СН-6	СН-7	СН-8	СН-9	СН-10	СН-11	CH-12



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Post Ca	libration o	of Senso	r at 350)°C										
Date Time CH-1 CH-2 CH-3 CH-4 CH-5 CH-6 CH-7 CH-8 CH-9 CH-10 CH-11 CH-12													СН-12	
Accepta	nce criter	ia:												
	ature shoul		fluctua	ting moi	re than =	± 1°C fr	om the	mean of	tempera	atures sł	nown by	the cali	brated	
thermon	neter during	g the dat	ta-loggii	ng perio	d.									
Checked (Produc									Verifie (Quality	ty Assu	rance)			
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Inferen	ce:													
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7.9 Heat Distribution Study For Empty Chamber:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	

Empty Heat Distribution Cycle Parameter:

Parameters	Set Value	Observed Value				
Tarameters	Set value	1 st Cycle	2 nd Cycle	3 rd Cycle		
Cycle Start Date / Time						
Relative Humidity of Area						
No. of In - built Temp. Sensors	05					
No. of external placed Temp.	12					
Sensors						
Set Point 1 (Heater Bank 1 cut off)	330°C					
Set Point 2 (Heater Bank 1 cut off)	332°C					
Set Point 3 (Heater Bank 1 cut off)	334°C					
Set Point 4 (Heater Bank 1 cut off)	336°C					
Set Point 5 (Heater Bank 1 cut off)	338°C					
Set Point 6 (Heater Bank 1 cut off)	345°C					
Conveyor Start Temp.	310°C					
Conveyor Stop Temp.	305°C					
Conveyor Belt Speed	140 mm/min					



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Parameters	Set Value	Observed Value			
1 arameters	Set value	1st Cycle	2 nd Cycle	3 rd Cycle	
Pressure differentials (Drying	05-15 mm wc				
Zone)					
Pressure differentials (Sterilization	17-25 mm wc				
Zone)					
Pressure differentials (Cooling	05-15 mm wc				
Zone)					
Minimum Avg. Temperature (Sensor	No.& its				
Location)					
Maximum Avg. Temperature(Sensor	No.& its				
Location)					
Total Cycle Time					
Sterilization Zone Exposure Time					
Result					
Cold Spot (external placed Temp. Ser					
Cycle End Date / Time					

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	Ü
	Reviewed By
	(Manager QA) Sign/Date:
	Sign/Date.



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7.10 Heat Distribution Study For Loaded Chamber:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	

Loaded heat distribution cycle parameter:

Parameters	Set Value	Observed Value				
rarameters	Set value	1st Cycle	2 nd Cycle	3 rd Cycle		
Cycle Start Date / Time						
Relative Humidity of Area						
No. of external placed Temp.	12					
Sensors						
No. of In - built Temp. Sensors	05					
Set Point 1 (Heater Bank 1 cut off)	330°C					
Set Point 2 (Heater Bank 1 cut off)	332°C					
Set Point 3 (Heater Bank 1 cut off)	334°C					
Set Point 4 (Heater Bank 1 cut off)	336°C					
Set Point 5 (Heater Bank 1 cut off)	338°C					
Set Point 6 (Heater Bank 1 cut off)	345°C					
Conveyor Start Temp.	310°C					
Conveyor Stop Temp.	305°C					



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Parameters	Set Value		Observed Value			
1 at ameters	Set value	1st Cycle	2 nd Cycle	3 rd Cycle		
Conveyor Belt Speed	120 mm /					
	minute					
Pressure differentials (Drying Zone)	05-15 mm wc					
Pressure differentials (Sterilization	17-25 mm wc					
Zone)						
Pressure differentials (Cooling	05-15 mm wc					
Zone)						
Minimum Avg. Temperature (Sensor I	No.& its					
Location)						
Maximum Avg. Temperature(Sensor N	No.& its					
Location)						
Total Cycle Time						
Sterilization Zone Exposure Time						
Result						
Cold Spot (external placed Temp. Sens	sors)					
Cycle End Date / Time						
Checked By			Verified By			
(Production) Sign/Date:			(Quality Assurance) Sign/Date:			
Inference:						
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			Reviewed By (Manager QA Sign/Date:			



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7.11 Heat distribution study for loaded chamber:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	10 ml.

Loaded heat distribution cycle parameter:

Parameters	Set Value	Observed Value				
rarameters	Set value	1st Cycle	2 nd Cycle	3 rd Cycle		
Cycle Start Date / Time						
Relative Humidity of Area						
No. of external placed Temp. Sensors	12					
No. of In - built Temp. Sensors	05					
Set Point 1 (Heater Bank 1 cut off)	330°C					
Set Point 2 (Heater Bank 1 cut off)	332°C					
Set Point 3 (Heater Bank 1 cut off)	334 ⁰ C					
Set Point 4 (Heater Bank 1 cut off)	336°C					
Set Point 5 (Heater Bank 1 cut off)	338 ⁰ C					
Set Point 6 (Heater Bank 1 cut off)	345°C					
Conveyor Start Temp.	310°C					
Conveyor Stop Temp.	305°C					
Conveyor Belt Speed	120 mm /					
	minute					
Pressure differentials (Drying Zone)	05-15 mm					
	wc					
Pressure differentials (Sterilization	17-25 mm					



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Parameters	Set Value	Observed Value			
1 urumeters	Set value	1 st Cycle	2 nd Cycle	3 rd Cycle	
Zone)	wc				
Pressure differentials (Cooling Zone)	05-15 mm				
	wc				
Minimum Avg. Temperature (Sensor No.	.& its				
Location)					
Maximum Avg. Temperature(Sensor No.& its					
Location)					
Total Cycle Time					
Sterilization Zone Exposure Time					
Result					
Cold Spot (external placed Temp. Sensors)					
Cycle End Date / Time					

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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7.12 HEAT DISTRIBUTION STUDY FOR LOADED CHAMBER:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	20 ml

${\bf Loaded\ Heat\ Distribution\ Cycle\ Parameter:}$

Parameters	Set Value	Observed Value			
1 at affecters	Set value	1st Cycle	2 nd Cycle	3 rd Cycle	
Cycle Start Date / Time	•				
Relative Humidity of Area					
No. of external placed Temp.	12				
Sensors					
No. of In - built Temp. Sensors	05				
Set Point 1 (Heater Bank 1 cut off)	330°C				
Set Point 2 (Heater Bank 1 cut off)	332°C				
Set Point 3 (Heater Bank 1 cut off)	334°C				
Set Point 4 (Heater Bank 1 cut off)	336°C				
Set Point 5 (Heater Bank 1 cut off)	338°C				
Set Point 6 (Heater Bank 1 cut off)	345°C				
Conveyor Start Temp.	310°C				



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D	G	Observed Value			
Parameters	Set Value	1 st Cycle	2 nd Cycle	3 rd Cycle	
Conveyor Stop Temp.	305°C				
Conveyor Belt Speed	110 mm / min				
Pressure differentials (Drying Zone)	05-15 mm wc				
Pressure differentials (Sterilization Zone)	17-25 mm wc				
Pressure differentials (Cooling Zone)	05-15 mm wc				
Minimum Avg. Temperature (Sensor I	No.& its				
Maximum Avg. Temperature(Sensor I	No.& its				
Total Cycle Time					
Sterilization Zone Exposure Time					
Result					
Cold Spot (external placed Temp. Sens	sors)				
Cycle End Date / Time					
Checked By (Production) Sign/Date:			Verified By (Quality Assur Sign/Date:	rance)	
Inference:					
			Reviewed By (Manager QA) Sign/Date:		



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7.13 Heat penetration study for loaded chamber:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	5 ml.

LOADED HEAT PANETRATION CYCLE PARAMETER:

Parameters	Set Value	Observed Value			
1 arameters	Set value			3 rd Cycle	
Cycle Start Date / Time	1				
Relative Humidity of Area					
No. of external placed Temp. Sensors	12				
No. of In - built Temp. Sensors	05				
Set Point 1 (Heater Bank 1 cut off)	330°C				
Set Point 2 (Heater Bank 1 cut off)	332°C				
Set Point 3 (Heater Bank 1 cut off)	334°C				
Set Point 4 (Heater Bank 1 cut off)	336°C				
Set Point 5 (Heater Bank 1 cut off)	338°C				
Set Point 6 (Heater Bank 1 cut off)	345°C				
Conveyor Start Temp.	310°C				
Conveyor Stop Temp.	305°C				
Conveyor Belt Speed	120 mm /				
	min				



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Parameters	Set Value	Observed Value				
Tarameters	Set value	1 st Cycle	2 nd Cycle	3 rd Cycle		
Pressure differentials (Drying Zone)	05-15 mm					
	wc					
Pressure differentials (Sterilization	17-25 mm					
Zone)	wc					
Pressure differentials (Cooling Zone)	05-15 mm					
	wc					
Minimum Avg. Temperature (Sensor No	o.& its					
Location)						
Maximum Avg. Temperature(Sensor No	o.& its					
Location)						
Total Cycle Time						
Sterilization Zone Exposure Time						
Result						
Cold Spot (external placed Temp. Senso	rs)					
Cycle End Date / Time						
Checked By (Production) Sign/Date:			Verified By (Quality Assu Sign/Date:	rance)		
Inference:						
			Reviewed By (Manager QA) Sign/Date:			



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7.14 F_H Calculation & Endotoxin Test Report:

Probe No.		ogenating oerature	Duration of Do Ten (300°C &	np.	F _H Value	Reduction of Endotoxin	Remarks
	Max	Min	From	To			
	nce Criteria n of Endotoxi						
Checked (Produc					Verified (Onelity	By Assurance)	
	ite:				Sign/Dat	e:	
Inference	ce:						
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7.15 HEAT PANETRATION STUDY FOR LOADED CHAMBER:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	10 ml.

Loaded heat penetration cycle parameter:

	G . 77 7	O	Observed Value	
Parameters	Set Value	1st Cycle	Diserved Value 2nd Cycle	3 rd Cycle
Cycle Start Date / Time				
Relative Humidity of Area				
No. of external placed Temp. Sensors	12			
No. of In - built Temp. Sensors	05			
Set Point 1 (Heater Bank 1 cut off)	330°C			
Set Point 2 (Heater Bank 1 cut off)	332°C			
Set Point 3 (Heater Bank 1 cut off)	334°C			
Set Point 4 (Heater Bank 1 cut off)	336 ⁰ C			
Set Point 5 (Heater Bank 1 cut off)	338°C			
Set Point 6 (Heater Bank 1 cut off)	345°C			
Conveyor Start Temp.	310°C			
Conveyor Stop Temp.	305°C			
Conveyor Belt Speed	120 mm / min			
Pressure differentials (Drying Zone)	05-15 mm			
Pressure differentials (Sterilization Zone)	17-25 mm wc			
Pressure differentials (Cooling Zone)	05-15 mm wc			



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D.	Set Value	Observed Value				
Parameters	Set value	1st Cycle	2 nd Cycle	3 rd Cycle		
Minimum Avg. Temperature (Sensor No.& its	Location)					
Maximum Avg. Temperature(Sensor No.& its	Location)					
Total Cycle Time						
Sterilization Zone Exposure Time						
Result						
Cold Spot (external placed Temp. Sensors)						
Cycle End Date / Time						

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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Probe No.	De-pyrog Tempe		Ter	epyrogenating np. & Above)	F _H Value	Reduction of Endotoxin	Remarks
	Max	Min	From	To			
Accepta	nce Criteria:		•				
Reduction	n of Endotoxin	NLT 3 log					
Chaolro	J D.,				Von	fied Dw	
Checked (Produc						fied By ality Assurance)	
	te:					n/Date:	
2- 8 , w					~-8-		
Inference	ce:						
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						iewed By	
						nager QA) n/Date:	



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7.17 HEAT PANETRATION STUDY FOR LOADED CHAMBER:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	20 ml.

LOADED HEAT PANETRATION CYCLE PARAMETER:

Parameters	Set Value	Observed Value				
1 at afficiets	Set value	1st Cycle	2 nd Cycle	3 rd Cycle		
Cycle Start Date / Time						
Relative Humidity of Area						
No. of external placed Temp. Sensors	12					
No. of In - built Temp. Sensors	05					
Set Point 1 (Heater Bank 1 cut off)	330°C					
Set Point 2 (Heater Bank 1 cut off)	332°C					
Set Point 3 (Heater Bank 1 cut off)	334°C					
Set Point 4 (Heater Bank 1 cut off)	336°C					
Set Point 5 (Heater Bank 1 cut off)	338°C					
Set Point 6 (Heater Bank 1 cut off)	345°C					
Conveyor Start Temp.	310°C					
Conveyor Stop Temp.	305°C					
Conveyor Belt Speed	120 mm / min					
Pressure differentials (Drying Zone)	05-15 mm wc					
Pressure differentials (Sterilization	17-25 mm wc					
Zone)						
Pressure differentials (Cooling Zone)	05-15 mm wc					
Minimum Avg. Temperature (Sensor No	o.& its Location)					



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Parameters	Set Value	Observed Value				
- W. W	2 00 (0.200	1 st Cycle	2 nd Cycle	3 rd Cycle		
Maximum Avg. Temperature(Sensor No.						
Total Cycle Time						
Sterilization Zone Exposure Time						
Result						
Cold Spot (external placed Temp. Sensor						
Cycle End Date / Time						

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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7.18 F_H Calculation & Endotoxin Test Report:

Probe No.		ogenating perature	pyrogenating Temp. (300°C & Above)		F _H Value	Reduction of Endotoxin	Remarks
	Max	Min	From	To			
	•	•				1	
Accenta	nce Criteria	 a:					
	n of Endotoxi						
Checked (Produc Sign/Da						By Assurance)	
Inferen	ce:						
•••••	••••••						•••••
						•••••	•••••
	• • • • • • • • • • • • • • • • • • • •						•••••
					Reviewe	d By	
					(Manage	er QA)	
					Sign/Dat	e:	



${\sf PR}$	O	\mathbf{T}	O	C	O	L	N	0.	
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8.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates for Anemometer.
- Calibration Certificates for Airborne particle counter.
- Calibration Certificates for Aerosol Photometer.
- Calibration Certificate of Data logger.
- Calibration Certificate of Sensors.
- Certificate of Analysis for LAL.

9.0	NON COMPLIANCE:
10.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:
11.0	CHANGE CONTROL, IF ANY:



P	R	0	\mathbf{T}	O	\mathbf{C}	0	L	N	0	

ГПА	ARMA DEVILS	
12.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	
		•••••
13.0	CONCLUSION	
1010	667,6263267	
14.0	RECOMMENDATION	
	•••••••••••••••••••••••••••••••••••••••	



PERFORMANCE QUALIFICATION REPORT FOR

PROTOCOL No.:

STERILIZINF & DEPYROGENATING TUNNEL

15.0 ABBREVIATIONS:

No. : Number

WHO : World Health Organization

FDA : Food and Drug Administration

CFR : Code of Federal Regulations

cGMP : Current Good Manufacturing Practices

QA : Quality Assurance

SOP : Standard Operating Procedure

mm : Millimeter

Amp. : Ampere

DQ : Design Qualification

IQ : Installation Qualification

OQ : Operational Qualification

PQ : Performance Qualification

FBD : Sterilizing & Depyrogenating Tunnel

SOP : Standard Operating Procedure

BMR : Batch Manufacturing Record



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16.0 REPORT POST 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)			