

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

EQUIPMENT ID. No.	
LOCATION	Unit Preparation Room
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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	Pre-Approval Objective Scope Responsibility Equipment Details Pre-Qualification Requirement Tests & Checks Checklist of All Tests And Checks Documents To Be Attached Non Compliance Deviation From Pre-Defined Specification, If Any Change Control, If Any Review Inclusive of Follow Up Action, If Any Conclusion Recommendations Abbreviations



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1.0 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)			



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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 **Autoclave Cum Bung Processor**, installed in **Unit Preparation Room**.
- 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 overall compliance of this Report:

DEPARTMENTS	RESPONSIBILITIES		
Quality Assurance	Preparation, Authorization, Approval and Compilation of the		
	Performance Qualification Review of Report.		
	Co-ordination with Quality Control, Production and Engineering to		
	carryout Performance Qualification Activity.		
	Monitoring of Performance Qualification.		
Production	Review of Report.		
	• To co-ordinate and support Performance Qualification Activity.		
Quality Control	Review of Report.		
	 Analytical Support (Microbiological Testing/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.		



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5.0 EQUIPMENT DETAILS:

Equipment Name	Autoclave Cum Bung Processor
Equipment	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Unit Preparation Room

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 Autoclave cum Bung Processor.
- SOP for Preventive Maintenance of Autoclave cum Bung Processor.



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7.0	TESTS	AND	CHECKS:
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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 Autoclave				
	Cum Bung Processor				
6.	SOP for Preventive				
	Maintenance of Autoclave				
	Cum Bung Processor				

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



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7.2 VACUUM LEAD	K TEST:			
Vacuum Leak Test Details				
Equipment Name				
Equipment Make				
Equipment ID No.				
Date				
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3
Pre Vacuum	- 0.600 Bar			
Delay before Hold	5 Minute			
Vacuum Hold time	10 Minute			
Acceptable Leakage	0.013 Bar			
Actual Leakage				
Process End Pressure	- 0.030 Bar			
Cycle Started				
Cycle Completed				
			1	
Checked By (Production) Sign/Date:				sy Assurance)
Inference:				
			Reviewed (Manager Sign/Date	



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7.3 BOWIE - DICK TEST:

Bowie Dick Test Details		
Equipment Name		
Equipment Make		
Equipment ID No.		
Date		

Parameters	Set Value	Observed Value			
1 arameters		Cycle - 1	Cycle - 2	Cycle - 3	
Cycle Start Date & Tim	ne				
Pre Vacuum	- 0.500 Bar				
Pre Pressure	0.500 Bar				
No. of Pre Pulses	03 Nos.				
Heat up 1	110°C				
Heat up hold 1	5 Minute				
Heat up 2	115 °C				
Heat up hold 2	3 Minute				
Heat up 3	119°C				
Heat up hold 3	2 Minute				
Heat up control band	0.2 °C				
Small valve SP	120.0°C				



Parameters

PHARMA DEVILS

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Set Value

Observed Value

		Cycle - 1	Cycle - 2	Cycle - 3
Sterilization Hold Temperature	121.4 °C			
Sterilization Hold Time	17 Minute			
Control band	0.3 °C			
Overshoot Temperature	124.0 °C			
Sterilization Stop Temperature	120.9 °C			
Sterilization Reset Temperature	120.5 °C			
Process End Pressure	0.040 Bar			
Exhaust ON	5 Sec.			
Exhaust OFF	60 Sec.			
Cycle End Date & Time	2			
Observation of Color ch	nange in Bowie			
Dick Pack				
Checked By			Verified B	
(Production)			(Quality A	
Sign/Date:	•••••		Sign/Date	
Inference:				
	•••••			•••••
	•••••		Reviewed 1	 By
			(Manager	QA)
			Sign/Date:	



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R	Atta	ch ick Test
В	Indica	
	Indica	ltor
Observation:		
ecked By roduction)		Verified By (Quality Assurance) Sign/Date
gn/Date:		
erence:		
erence:		

Sign/Date:



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At	tach
Bowie -	Dick Test
Indi	icator
	icator
Observation:	
necked By roduction) gn/Date:	Verified By (Quality Assurance) Sign/Date
erence:	
	Reviewed By (Manager QA) Sign/Date:



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Bowie -	ttach Dick Test icator
Observation:	
Checked By Production) ign/Date:	Verified By (Quality Assurance) Sign/Date
	Reviewed By (Manager OA)

Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.4 HEAT DISTRIBUTION STUDY FOR STANDARD:

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

_			Observed Value	ie	
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3	
Cycle Start Date & Tin	ne				
Pre Vacuum	0.00 bar				
Pre Pressure	0.00 bar				
No. of pre pulses	0 Nos.				
Heat up 1	110.0 °C				
Heat up hold 1	5 Minute				
Heat up 2	115.0°C				
Heat up hold 2	3 Minute				
Heat up 3	118.0 °C				
Heat up hold 3	2 Minute				
Heat up control band	0.3 °C				
Small valve SP	120 °C				
Sterilization Hold Temperature	121.4°C				
Sterilization Hold time	30 Minute				
Control band	0.3 °C				



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		Observed Value			
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3	
Overshoot Temperature	124.0 °C				
Sterilization Stop Temperature	120.0 °C				
Sterilization Reset Temperature	119.0 °C				
Exhaust ON	10 Sec.				
Exhaust OFF	20 Sec.				
Cycle End Date & Tin	ne				

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



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7.5 HEAT DISTRIBUTION STUDY FOR HPHV PROCESS (EMPTY CHAMBER):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	Cot Volue	Observed Value		
rarameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3
Cycle Start Date & Time				
Pre Vacuum	- 0.500 Bar			
Pre Pressure	0.500 Bar			
No. of Pre pulses	3 Nos.			
Heat up 1	110°C			
Heat up hold 1	5 Minute			
Heat up 2	115.0 °C			
Heat up hold 2	3 Minute			
Heat up 3	119.0 °C			
Heat up hold 3	2 Minute			
Heat up band	0.2 °C			
Small valve set point	120.0 °C			
Sterilization Hold Temperature	121.4 °C			
Sterilization Hold time	30 Minute			
Temperature Control band	0.3 °C			



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Parameters	Set Value	Observed Value		
		Cycle - 1	Cycle - 2	Cycle - 3
Overshoot Temperature	124.0 °C			
Sterilization Stop Temperature	120.0 °C			
Sterilization Reset Temperature	119.5 °C			
Post vacuum start press.	0.200 Bar			
Post vacuum	-0.600 Bar			
Post vacuum hold time	10 Minute			
No. of post pulses	3 Nos.			
Process End Pressure	-0.500 Bar			
Exhaust ON	5 Sec.			
Exhaust OFF	50 Sec.			
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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7.6 HEAT PENETRATION STUDY H.P.H.V. (GARMENT LOADED CHAMBER) (MAXIMUM):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	C-4 V-1	Observed Value		
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3
Cycle Start Date & Time				
Pre Vacuum	- 0.500 Bar			
Pre Pressure	0.500 Bar			
No. of Pre pulses	3 Nos.			
Heat up 1	110°C			
Heat up hold 1	5 Minute			
Heat up 2	115.0 °C			
Heat up hold 2	3 Minute			
Heat up 3	119.0 °C			
Heat up hold 3	2 Minute			
Heat up band	0.2 °C			
Small valve set point	120.0 °C			
Sterilization Hold Temperature	121.4 °C			
Sterilization Hold time	30 Minute			
Temperature Control band	0.3 °C			



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Parameters	Set Value	Observed Value			
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3	
Overshoot Temperature	124.0 °C				
Sterilization Stop Temperature	120.0 °C				
Sterilization Reset Temperature	119.5 °C				
Post vacuum start press.	0.200 Bar				
Post vacuum	-0.600 Bar				
Post vacuum hold time	10 Minute				
No. of post pulses	3 Nos.				
Exhaust ON	5 Sec.				
Exhaust OFF	50 Sec.				
Process End pressure	-0.500 Bar				
Cycle End Date & Time					

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



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7.6.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip							
S.No.	Observation	S.No.	Observation	Remark			
Checked (Product Sign/Dat			Verified By (Quality Assuran Sign/Date	ce)			
Inference:							
		•	Reviewed By (Manager QA) Sign/Date:				



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.6.2 Fo CALCULATION:

Probe	Sterili Tempera	Sterilizing Temperature (°C)		F _o Value Spore Log Reduction		Reduction		Chemical
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status	Indicator Status

Checked F (Production Sign/Dates	-					l By y Assurance) ate	
Inference:							
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7.7 HEAT PENETRATION STUDY H.P.H.V. (MIXED LOADED CHAMBER):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	Set Value	Observed Value		
Parameters		Cycle - 1	Cycle - 2	Cycle - 3
Cycle Start Date & Time				
Pre Vacuum	- 0.500 Bar			
Pre Pressure	0.500 Bar			
No. of Pre Pulses	3 Nos.			
Heat up 1	110°C			
Heat up hold 1	5 Minute			
Heat up 2	115.0 °C			
Heat up hold 2	3 Minute			
Heat up 3	119.0 °C			
Heat up hold 3	2 Minute			
Heat up band	0.2 °C			
Small valve set point	120.0 °C			
Sterilization Hold Temperature	121.4 °C			
Sterilization Hold time	30 Minute			
Temperature Control band	0.3 °C			



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Parameters	Set Value		Observed Value	
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3
Overshoot Temperature	124.0 °C			
Sterilization Stop Temperature	120.0 °C			
Sterilization Reset Temperature	119.5 °C			
Post vacuum start press.	0.200 Bar			
Post vacuum	-0.600 Bar			
Post vacuum hold time	10 Minute			
No. of post pulses	3 Nos.			
Exhaust ON	5 Sec.			
Exhaust OFF	50 Sec.			
Process End Pressure	-0.500 Bar			
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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.7.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip							
S. No.	Observation	S. No.	Observation	Remark			
Checked (Product			Verified By (Quality Assuran Sign/Date	ce)			
Inference			Signi Zuteriii				
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			Reviewed By (Manager QA) Sign/Date:				



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7.7.2 Fo CALCULATION:

Probe		ture (°C)		'alue		Reduction	Biological Indicator	Chemical Indicator
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Status	Status

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



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7.8 HEAT PENETRATION STUDY H.P.H.V. (ACCESSORIES LOADED CHAMBER):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	Set Value			
rarameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3
Cycle Start Date & Time				
Pre Vacuum	- 0.500 Bar			
Pre Pressure	0.500 Bar			
No. of Pre Pulses	3 Nos.			
Heat up 1	110°C			
Heat up hold 1	5 Minute			
Heat up 2	115.0 °C			
Heat up hold 2	3 Minute			
Heat up 3	119.0 °C			
Heat up hold 3	2 Minute			
Heat up band	0.2 °C			
Small valve set point	120.0 °C			
Sterilization Hold Temperature	121.4 °C			
Sterilization Hold time	30 Minute			
Temperature Control band	0.3 °C			



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Parameters	Set Value	Observed Value				
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
Overshoot Temperature	124.0 °C					
Sterilization Stop Temperature	120.0 °C					
Sterilization Reset Temperature	119.5 °C					
Post vacuum start press.	0.200 Bar					
Post vacuum	-0.600 Bar					
Post vacuum hold time	10 Minute					
No. of post pulses	3 Nos.					
Exhaust ON	5 Sec.					
Exhaust OFF	50 Sec.					
Process End Pressure	-0.500 Bar					
Cycle End Date & Time						

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



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.8.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip							
S. No.	Observation	S. No.	Observation	Remark			
Checked (Product Sign/Dat	By ion) e:	ı	Verified By (Quality Assuran Sign/Date	ce)			
Inference	2:						
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			Reviewed By (Manager QA)				



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7.8.2 Fo CALCULATION:

Probe	Steril Tempera	izing ture (°C)	F _o V	alue	Spore Log Reduction			Chemical
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status	Indicator Status

(Productio	Checked By Production) Sign/Date:				Verified By (Quality Assurance) Sign/Date				
Inference:									
•••••			•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	••••••	• • • • • • • • • • • • • • • • • • • •	•••••	
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7.9 HEAT PENETRATION STUDY H.P.H.V. (BLENDER LOADED CHAMBER):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	Set Value		Observed Value			
Parameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
Cycle Start Date & Time						
Pre Vacuum	- 0.500 Bar					
Pre Pressure	0.500 Bar					
No. of Pre pulses	3 Nos.					
Heat up 1	110°C					
Heat up hold 1	5 Minute					
Heat up 2	115.0 °C					
Heat up hold 2	3 Minute					
Heat up 3	119.0 °C					
Heat up hold 3	2 Minute					
Heat up band	0.2 °C					
Small valve set point	120.0 °C					
Sterilization Hold Temperature	121.4 °C					
Sterilization Hold time	30 Minute					
Temperature Control band	0.3 °C					



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Parameters	Set Value		Observed Value			
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
Overshoot Temperature	124.0 °C					
Sterilization Stop Temperature	120.0 °C					
Sterilization Reset Temperature	119.5 °C					
Post vacuum start press.	0.200 Bar					
Post vacuum	-0.600 Bar					
Post vacuum hold time	10 Minute					
No. of post pulses	3 Nos.					
Process End Pressure	-0.500 Bar					
Exhaust ON	5 Sec.					
Exhaust OFF	50 Sec.					
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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7.9.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip							
S. No.	Observation	S. No.	Observation	Remark			
Checked By (Production) (Sign/Date: Sign/Date:							
Inference:							
	Reviewed By (Manager QA)						



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7.9.2 F₀ **CALCULATION**:

Probe	Steril Tempera	ture (°C)	F _o V	F _o Value Spore Log Reduction		Reduction		Chemical
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status	Indicator Status

Checked By (Production) Sign/Date:					Verified By (Quality Assurance) Sign/Date				
Inference:									
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7.10 HEAT PENETRATION STUDY H.P.H.V. (FLIP OFF SEAL LOADED CHAMBER) (MINIMUM):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	Set Value	Observed Value				
Parameters		Cycle - 1	Cycle - 2	Cycle - 3		
Cycle Start Date & Time						
Pre Vacuum	- 0.500 Bar					
Pre Pressure	0.500 Bar					
No. of Pre pulses	3 Nos.					
Heat up 1	110°C					
Heat up hold 1	5 Minute					
Heat up 2	115.0 °C					
Heat up hold 2	3 Minute					
Heat up 3	119.0 °C					
Heat up hold 3	2 Minute					
Heat up band	0.2 °C					
Small valve set point	120.0 °C					
Sterilization Hold Temperature	121.4 °C					
Sterilization Hold time	30 Minute					
Temperature Control band	0.3 °C					



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Parameters	Set Value		Observed Value			
Tarameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
Overshoot Temperature	124.0 °C					
Sterilization Stop Temperature	120.0 °C					
Sterilization Reset Temperature	119.5 °C					
Post vacuum start press.	0.200 Bar					
Post vacuum	-0.600 Bar					
Post vacuum hold time	10 Minute					
No. of post pulses	3 Nos.					
Process End Pressure	-0.500 Bar					
Exhaust ON	5 Sec.					
Exhaust OFF	50 Sec.					
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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7.10.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip								
S. No.	Observation	S. No.	Observation	Remark				
Checked By (Production) Sign/Date: Inference: Verified By (Quality Assurance) Sign/Date Sign/Date								
•••••								
•••••	Reviewed By							

(Manager QA)

Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.10.2 Fo CALCULATION:

Probe		ture (°C)	F _o Value		Spore Log Reduction		Biological Indicator	Chemical Indicator
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Status	Status

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



QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.11 HEAT PENETRATION STUDY H.P.H.V. (FLIP OFF SEAL LOADED CHAMBER) (MAXIMUM):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	Set Value	Observed Value					
r arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3			
Cycle Start Date & Time							
Pre Vacuum	- 0.500 Bar						
Pre Pressure	0.500 Bar						
No. of Pre pulses	3 Nos.						
Heat up 1	110°C						
Heat up hold 1	5 Minute						
Heat up 2	115.0 °C						
Heat up hold 2	3 Minute						
Heat up 3	119.0 °C						
Heat up hold 3	2 Minute						
Heat up band	0.2 °C						
Small valve set point	120.0 °C						
Sterilization Hold Temperature	121.4 °C						
Sterilization Hold time	30 Minute						



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Parameters	Set Value		Observed Value				
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3			
Temperature Control band	0.3 °C						
Overshoot Temperature	124.0 °C						
Sterilization Stop Temperature	120.0 °C						
Sterilization Reset Temperature	119.5 °C						
Post vacuum start press.	0.200 Bar						
Post vacuum	-0.600 Bar						
Post vacuum hold time	10 Minute						
No. of post pulses	3 Nos.						
Process End Pressure	-0.500 Bar						
Exhaust ON	5 Sec.						
Exhaust OFF	50 Sec.						
Cycle End Date & Time							

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



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.11.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip						
S. No.	Observation	S. No.	Observation	Remark		
Checked By (Production) (Quality Assurance) Sign/Date: Sign/Date.						
	Inference:					
	Reviewed By (Manager QA)					

Sign/Date:



QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.11.2 Fo CALCULATION:

Probe	Sterilizing De Temperature (°C)			F _o Value		Spore Log Reduction		Chemical
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status	Indicator Status

Checked By Production) (Quality Assurance) Sign/Date: Sign/Date. Reviewed By (Manager QA) Sign/Date:							
Reviewed By (Manager QA)	(Production Sign/Date Inference:	on) :			(Quality Sign/Da	Assurance)	
Reviewed By (Manager QA)	• • • • • • • • • • • • • • • • • • • •	•••••					
Reviewed By (Manager QA)			 		 		•••••
Reviewed By (Manager QA)			 	•••••	 		•••••
					 Reviewe (Manag	ed By er QA)	



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.12 HEAT PENETRATION STUDY H.P.H.V. (BUNG LOADED CHAMBER) (MINIMUM):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	Set Value	Observed Value				
Parameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
Cycle Start Date & Time						
Pre Vacuum	- 0.500 Bar					
Pre Pressure	0.500 Bar					
No. of Pre pulses	3 Nos.					
Heat up 1	110°C					
Heat up hold 1	5 Minute					
Heat up 2	115.0 °C					
Heat up hold 2	3 Minute					
Heat up 3	119.0 °C					
Heat up hold 3	2 Minute					
Heat up band	0.2 °C					
Small valve set point	120.0 °C					
Sterilization Hold Temperature	121.4 °C					
Sterilization Hold time	30 Minute					
Temperature Control band	0.3 °C					



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Parameters	Set Value		Observed Value				
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3			
Overshoot Temperature	124.0 °C						
Sterilization Stop Temperature	120.0 °C						
Sterilization Reset Temperature	119.5 °C						
Post vacuum start press.	0.200 Bar						
Post vacuum	-0.600 Bar						
Post vacuum hold time	10 Minute						
No. of post pulses	3 Nos.						
Process End Pressure	-0.500 Bar						
Exhaust ON	5 Sec.						
Exhaust OFF	50 Sec.						
Cycle End Date & Time	•						

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



QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.12.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

	Status of Chemical Indicator Strip						
S. No.	Observation	S. No.	Observation	Remark			
Checked By (Production) Verified By (Quality Assurance)							
Sign/Date: Sign/Date Inference:							
			Reviewed By (Manager QA)				

Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.12.2 Fo CALCULATION:

Probe	Sterilizing Temperature (°C)			'alue		Reduction	Biological Indicator	Chemical Indicator
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Status	Status

Checked I (Production Sign/Date: Inference:	on) :				l By y Assurance) ate	
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		 	 	• • • • • • • • • • • • • • • • • • • •		
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				Reviewe	ed By	
				(Manag	•	
					ate:	



QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.13 HEAT PENETRATION STUDY H.P.H.V. (BUNG LOADED CHAMBER) (MAXIMUM):

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	C-4 V-1	Observed Value				
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3		
Cycle Start Date & Time						
Pre Vacuum	- 0.500 Bar					
Pre Pressure	0.500 Bar					
No. of Pre pulses	3 Nos.					
Heat up 1	110°C					
Heat up hold 1	5 Minute					
Heat up 2	115.0 °C					
Heat up hold 2	3 Minute					
Heat up 3	119.0 °C					
Heat up hold 3	2 Minute					
Heat up band	0.2 °C					
Small valve set point	120.0 °C					
Sterilization Hold Temperature	121.4 °C					
Sterilization Hold time	30 Minute					
Temperature Control band	0.3 °C					



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Parameters	rameters Set Value		Observed Value				
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3			
Overshoot Temperature	124.0 °C						
Sterilization Stop Temperature	120.0 °C						
Sterilization Reset Temperature	119.5 °C						
Post vacuum start press.	0.200 Bar						
Post vacuum	-0.600 Bar						
Post vacuum hold time	10 Minute						
No. of post pulses	3 Nos.						
Process End Pressure	-0.500 Bar						
Exhaust ON	5 Sec.						
Exhaust OFF	50 Sec.						
Cycle End Date & Time							

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



QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.13.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip								
S. No.	Observation	S. No.	Observation	Remark				
Checked By (Production) Sign/Date: Inference: Verified By (Quality Assurance) Sign/Date								
•••••	Raviawad Rv							

(Manager QA)

Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.13.2 Fo CALCULATION:

Probe		ture (°C)		'alue		Reduction	Biological Indicator	Chemical Indicator
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Status	Status

Checked By (Production) Sign/Date:				Verified By (Quality Assurance) Sign/Date				
Inference:								
						•••••		
	• • • • • • • • • • • • • • • • • • • •	•••••		••••••	•••••	•••••	•••••	
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					Reviewe	ed By	•••••	
					(Manag	er QA)		
					Sign/Da	ate:		



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.14 HEAT PENETRATION STUDY STANDARD (MEDIA LOADED):

Test Instrument Name	
Make	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Parameters	Set Value		Observed Value	
Parameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3
Cycle Start Date & Time				
Pre Vacuum	0.000 Bar			
Pre Pressure	0.000 Bar			
No. of Pre pulses	0 Nos.			
Heat up 1	110°C			
Heat up hold 1	5 Minute			
Heat up 2	115.0 °C			
Heat up hold 2	3 Minute			
Heat up 3	118.0 °C			
Heat up hold 3	2 Minute			
Heat up band	0.3 °C			
Small valve set point	120.0 °C			
Sterilization Hold Temperature	121.4 °C			
Sterilization Hold time	30 Minute			
Temperature Control band	0.3 °C			



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Parameters	Set Value		Observed Value	
1 diameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3
Overshoot Temperature	124.0 °C			
Sterilization Stop Temperature	120.0 °C			
Sterilization Reset Temperature	119.5 °C			
Process End Pressure	-0.050 Bar			
Exhaust ON	10 Sec.			
Exhaust OFF	20 Sec.			
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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.14.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip							
S. No.	Observation	S. No.	Observation	Remark			
Checked (Product Sign/Dat Inference	ion) e:		Verified By (Quality Assuran Sign/Date	ce)			
• • • • • • • • • •		•••••	Reviewed By				

(Manager QA)

Sign/Date:



QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.14.2 Fo CALCULATION:

Probe	Sterili Tempera	ture (°C)	F _o Value		Spore Log	Spore Log Reduction		Chemical Indicator
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status	Status

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



Test Instrument Name

PHARMA DEVILS

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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.15 BUNG PROCESSING AT MAXIMUM LOAD:

Make				
Sensors Type & Quantity				
Calibration done Date				
Calibration due Date				
Parameters	Set Value		Observed Value	
		Cycle - 1	Cycle - 2	Cycle - 3
Cycle Start Date & Time				
Wash - I				1
Machine wash	3 Minute			
Detergents fill Time	1 Minute			
Fluidization Time	10 Minute			
Delay for stabilization	5 Minute			
Purified water overflows	10 Minute			
Time				
Drain Time	5 Minute			
Machine wash	3 Minute			
Drain	5 Minute			
No. of Repeats	1 No.			
Wash - II		·		
Fluidization Time	10 Minute			
Delay for stabilization	5 Minute			



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Cot Value	Observed Value			
Set value	Cycle - 1	Cycle - 2	Cycle - 3	
10 Minute				
5 Minute				
3 Minute				
5 Minute				
1 No.				
5 Minute				
5 Minute				
3 Minute				
5 Minute				
1 No.				
1 Minute				
10 Minute				
5 Minute				
3 Minute				
5 Minute				
1 No.				
		1	1	
- 0.500 Bar				
0.500 Bar				
	5 Minute 3 Minute 5 Minute 1 No. 5 Minute 5 Minute 3 Minute 1 No. 1 Minute 10 Minute 5 Minute 5 Minute 10 Minute 1 No. 1 No.	Cycle - 1 10 Minute 5 Minute 5 Minute 1 No. 5 Minute 5 Minute 5 Minute 1 No. 1 Minute 1 No. 1 Minute 5 Minute 1 No. 1 No. 1 No. 1 No. 1 No. 1 No. 1 No. 1 No.	Cycle - 1 Cycle - 2	



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Parameters	Set Value	Observed Value		
Parameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3
No. of Pre pulses	3 Nos.			
Heat up 1	110°C			
Heat up hold 1	5 Minute			
Heat up 2	115.0 °C			
Heat up hold 2	3 Minute			
Heat up 3	119.0 °C			
Heat up hold 3	2 Minute			
Heat up band	0.2 °C			
Small valve set point	120.0 °C			
Sterilization Hold Temperature	121.4 °C			
Sterilization Hold time	30 Minute			
Temperature Control band	0.3 °C			
Overshoot Temperature	124.0 °C			
Sterilization Stop Temperature	120.0 °C			
Sterilization Reset Temperature	119.0 °C			
Post vacuum start press.	0.200 Bar			
Post Vacuum	-0.600 Bar			
Post Pressure	-0.100 Bar			
Post vacuum hold time	10 Minute			
No. of post pulses	3 Nos.			
Process End Pressure	-0.500 Bar			



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Parameters	Set Value	Observed Value		
T di dinette i s	Set value	Cycle - 1	Cycle - 2	Cycle - 3
Exhaust ON	0 Sec.			
Exhaust OFF	1 Sec.			
Chamber Water Temperature	30.0 °C			
Basket Drive ON	120 Sec.			
Basket Drive OFF	60 Sec.			
Cycle End Date & Time	1			

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



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of DQ, IQ & OQ &		
Other Documents.		
Verification of Machine Performance.		
vernication of Machine Performance.		
Checked By (Production)		Verified By (Ovelity Assurance)
(Production) Sign/Date:		(Quality Assurance) Sign/Date
•		•
Inference:		
		Daviawad Dv
		Reviewed By (Manager QA) Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

9.0 DOCUMENTS TO BE ATTACHED:

- Biological Indicator Incubation Report.
- Calibration Certificates for Data Logger.
- Calibration Certificates of Sensors.
- Printouts of Thermograph of all the cycles from Autoclave cum Bung Processor for time, temperature and pressure profile.
- LOD Report.
- Bungs Sterility Report

10.0	NON COMPLIANCE:
44.0	
11.0	DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:
12.0	CHANGE CONTROL, IF ANY:



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13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):
14.0	CONCLUSION:
15.0	RECOMMENDATION:

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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

16.0 ABBREVIATIONS:

WHO : World Health Organization

FDA : Food and Drug Administration

CFR : Code of Federal Regulations

cGMP : Current Good Manufacturing Practices

EU : European Union

QC : Quality Control

DQ : Design Qualification

IQ : Installation Qualification

OQ : Operational Qualification

PQ : Performance Qualification

SOP : Standard Operating Procedure

MOC : Material of Construction

NLT : Not Less Than

Sec. : Seconds

SS : Stainless Steel

ID. : Identification

mm : Mili meter

MCB : Miniature Circuit Breaker

ID : Inner Diameter



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

17.0 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)			