



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

**PERFORMANCE QUALIFICATION
REPORT
FOR
AUTOCLAVE CUM BUNG PROCESSOR**

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



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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)			



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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.



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Review of Report.• To co-ordinate and support Performance Qualification Activity.
Quality Control	<ul style="list-style-type: none">• Review of Report.• Analytical Support (Microbiological Testing/Analysis).
Engineering	<ul style="list-style-type: none">• Reviewing of qualification Report for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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.



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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 Autoclave Cum Bung Processor				
6.	SOP for Preventive Maintenance of Autoclave Cum Bung Processor				

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 AUTOCLAVE CUM BUNG PROCESSOR

7.2 VACUUM LEAK 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				

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 AUTOCLAVE CUM BUNG PROCESSOR

7.3 BOWIE - DICK TEST:

Bowie Dick Test Details

Equipment Name	
Equipment Make	
Equipment ID No.	
Date	

Parameters	Set Value	Observed 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	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			



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

Parameters	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				
Observation of Color change in Bowie Dick Pack				

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 AUTOCLAVE CUM BUNG PROCESSOR

**Attach
Bowie - Dick Test
Indicator**

Observation:

Checked By
(Production)
Sign/Date:

Inference:

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

Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

**Attach
Bowie - Dick Test
Indicator**

Observation:

**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 AUTOCLAVE CUM BUNG PROCESSOR

**Attach
Bowie - Dick Test
Indicator**

Observation:

**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 AUTOCLAVE CUM BUNG PROCESSOR

7.4 HEAT DISTRIBUTION STUDY FOR STANDARD:

Test Instrument Name	
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				
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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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	119.0 °C			
Exhaust ON	10 Sec.			
Exhaust OFF	20 Sec.			
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 AUTOCLAVE CUM BUNG PROCESSOR

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

Test Instrument Name	
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				
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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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:

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**Reviewed By
(Manager QA)**

Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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	Set Value	Observed 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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.6.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip				
S.No.	Observation	S.No.	Observation	Remark

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 AUTOCLAVE CUM BUNG PROCESSOR

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		
		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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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.			
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:

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Reviewed By
(Manager QA)
Sign/Date:



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 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 AUTOCLAVE CUM BUNG PROCESSOR

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	Observed 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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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



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 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 AUTOCLAVE CUM BUNG PROCESSOR

7.8.2 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical 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
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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		
		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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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:

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.9.2 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical 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
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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		
		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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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:

Inference:

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Verified By

(Quality Assurance)

Sign/Date:.....

Reviewed By

(Manager QA)

Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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:

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



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		
		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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

Parameters	Set Value	Observed 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:

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**Verified By
(Quality Assurance)**

Sign/Date:.....

**Reviewed By
(Manager QA)**

Sign/Date:



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)
Sign/Date:

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



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		
		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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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:

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Reviewed By
(Manager QA)
Sign/Date:



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)
Sign/Date:

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.12.2 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical 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
(Manager QA)
Sign/Date:



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	Set Value	Observed 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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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:

Inference:

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Verified By

(Quality Assurance)

Sign/Date:.....

**Reviewed By
(Manager QA)**

Sign/Date:



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:

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

7.14 HEAT PENETRATION STUDY STANDARD (MEDIA LOADED):

Test Instrument Name	
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				
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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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			
Process End Pressure	-0.050 Bar			
Exhaust ON	10 Sec.			
Exhaust OFF	20 Sec.			
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 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 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 AUTOCLAVE CUM BUNG PROCESSOR

7.15 BUNG PROCESSING AT MAXIMUM LOAD:

Test Instrument Name	
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				
Machine wash	3 Minute			
Detergents fill Time	1 Minute			
Fluidization Time	10 Minute			
Delay for stabilization	5 Minute			
Purified water overflows Time	10 Minute			
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			



PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

Parameters	Set Value	Observed Value		
		Cycle - 1	Cycle - 2	Cycle - 3
Purified water overflows Time	10 Minute			
Drain Time	5 Minute			
Machine wash	3 Minute			
Drain	5 Minute			
No. of Repeats	1 No.			
Wash - III				
Delay before drain time	5 Minute			
Drain Time	5 Minute			
Machine wash	3 Minute			
Drain	5 Minute			
No. of Repeats	1 No.			
SILICONIZATION				
Silicon in Time	1 Minute			
Silicon Soaking Time	10 Minute			
Drain Time	5 Minute			
Machine wash	3 Minute			
Drain	5 Minute			
No. of Repeats	1 No.			
STERILIZATION				
Pre Vacuum	- 0.500 Bar			
Pre Pressure	0.500 Bar			



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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

Parameters	Set Value	Observed 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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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

Parameters	Set Value	Observed 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				

**Checked By
(Production)**

Sign/Date:

Inference:

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Verified By

(Quality Assurance)

Sign/Date:

Reviewed By

(Manager QA)

Sign/Date:



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.		

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 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:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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PERFORMANCE QUALIFICATION REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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PERFORMANCE QUALIFICATION REPORT FOR 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



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)			