OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

HPHV STEAM STERILIZER

SIZE: 750 x 750 x 1200 mm

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER	PROTOCOL No.:

PROTOCOL CONTENTS

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

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2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of HPHV Steam sterilizer and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol Cum Report is limited to qualification of **HPHV Steam sterilizer (Make:…….)** installed in the **Unit Preparation Room**.
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity of Autoclave Cum Bung Processor.
- Successful completion of this Protocol Cum Report will verify that HPHV Steam sterilizer meet all acceptance criteria and ready for Performance Qualification.

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 Protocol Cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and compilation of the operational Qualification Protocol Cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Post Approval of Operational Qualification Protocol after Execution. • Monitoring of Operation Process.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol Cum Report. • Post Approval of Operational Qualification Protocol after Execution.
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Post Approval of Operational Qualification Protocol after Execution. • Calibration of Process Instruments.

5.0 EQUIPMENT DETAILS:

Equipment Name	HPHV steam sterilizer
Equipment	…
Manufacturer's Name	Machinfabrik
Supplier's Name	Machinfabrik
Location of Installation	Unit Preparation Room

6.0 EQUIPEMENT DESCRIPTION:

HPHV is a Jacketed Pressure Vessel. The Standard Steam Sterilization cycle is initiated by introducing Steam into the Jacket. This essentially aids in Preheating the Chamber and Effective Utilization of Heat Energy.

When a Particular Pressure inside the Jacket is achieved, Steam is introduced into the chamber. Air being heavier than Steam is displaced by Gravity Displacement Method which ensures Uniform Steam Distribution and Penetration. The equipment is also provided with Steam Traps with Air Vent to ensure Maximum Air Removal and Steam Condensate without allowing steam to pass through it.

As the Temperature of the Chamber increases, and reaches to the Sterilization Temperature, the control system in place controls this temperature for the Sterilization Time.

After the sterilization hold period is completed, steam from the chamber is exhausted to bring the chamber pressure to atmosphere.

The High pressure High Vacuum Steam Sterilization Process consists of following phases:-

- Vacuum steam pulsing
- Heat up
- Sterilization hold
- Vacuum drying
- Sterile air in

The Standard Steam Sterilization Process consists of following phases: -

- Heat up
- Sterilization hold
- Exhaust

A double door Steam Sterilizer is an industrial steam sterilizer especially designed for:

- Steam Sterilization of Garments.
- Steam Sterilization of Filtration Accessories.

- Steam Sterilization of Filling Machine Components, Manufacturing Accessories etc.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of HPHV Steam sterilizer.
- Draft SOP for Preventive Maintenance of HPHV Steam sterilizer.
- Electrical Circuits Diagram.
- Technical specification of equipment.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S. No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	Executed and approved Design Qualification document				
2.	Executed and approved Installation Qualification document				
3.	Draft SOP for Operation & Cleaning of HPHV Steam sterilizer.				
4.	Draft SOP for Preventive Maintenance of HPHV Steam sterilizer				

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8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On	Observed By Sign/Date

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8.3 OPEARATIONAL, AND FUNCTIONAL CHECKS:

OPERATIONAL CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Main Switch	When it is switch on all control works		
Jacket Steam	Upon keeping this switch in ON position steam enters to the jacket		
Chamber Steam	Upon keeping this switch in ON position steam enters to the chamber		
Chamber Steam Exhaust	Upon keeping this switch in ON position chamber steam, exhaust to atmospheric opens.		
Jacket Steam Exhaust	Upon keeping this switch in ON position jacket steam, exhaust to atmospheric opens.		
Chamber air vent	Upon keeping this switch in ON position chamber vacuum break & sterile air enters to the chamber.		

 PHARMA DEVILS	**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**	**PROTOCOL No.:**

OPERATIONAL CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Chamber vacuum valve	Upon keeping this switch in ON position r air inside chamber remove.		
Leakage	Should be less than 0.013 Bar		

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8.4 Verification of Safety & Interlocks:

Safety	Method	Required	Observation	Observed By (Engineering) Sign/Date
Opening of door during auto or manual mode	When process is running in auto or manual mode operation press unloading or loading door open push button one by one	Door should not open		
Both the door can not open simultaneously	When Unloading door is open , press loading door open push button	Loading door should not open		
Unloading door opening	Unloading door will open only after successful completion of process.	loading door should not open		
Door is opened	Keep unloading door open & start the process. Do not pressurize unloading door gasket & start the process. Close the both side door & do not pressurize any one of them door.	Process should not start		
Door obstruction	When door is moving obstruct the door with hand or material.	Door should move back.		
loading door open after process is aborted	After sterilization cycle is aborted, loading should be open. by pressing loading door open push button	loading door should open		

Unloading door should not open &loading door should open	After completion of unloading & unloading door acknowledge push button is pressed unloading door should not open & only loading side door should open	Unloading door should not open &loading door should open		

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8.5 Alarm Checks

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Leak test fail	• During vacuum hold period, open filter air in valve by operating manual over ride facility on SLV for some time & then shut off. • The vacuum will be broken.	At the end of process alarm will generate		
Over shooting of Temperature (Overshoot temp.)	• Set over shoot temperature set point 2^0C more than sterilization temperature & run the process. Let temp. Rise above over shoot temp. Set point.	Alarm will generate when chamber temperature crosses overshoot temperature & exhaust valve will open.		
Sterilization hold period counting stop (Ster. Stop temp.)	• During ster. hold period after five minutes, stop chamber incoming steam supply. So that chamber temperature will fall down to ster. stop temperature set point • Now, open	Alarm will generate & counting will Stop. when the chambers		

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
	chamber steam supply	temp. Attain sterilization temp. The counting will start further from where it was stopped (i.e. After five minute) & alarm will stop		
Sterilization hold period counting reset (Ster. Reset temp.)	During the sterilization hold period, stop chamber incoming steam supply so that chamber temperature will fall down below set point	Alarm will generate & counting will reset to zero		
	Now, open chamber steam supply	When the chamber attains sterilization hold temperature the time counting will start freshly (from zero) & alarm will stop.		
Chamber pressure high	Allow the chamber pressure to rise more than chamber pressure high set point by opening the steam in valve manually	Alarm will be generated & exhaust valve will open & message will be displayed on MMI		

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Too long time for pre vacuum	Set, TLT for pre vacuum set point less than actual required time (1 or 2 min.)	Alarm will be generated & message will displayed on MMI		
Too long time for post vacuum	Set, TLT for post vacuum set point less than actual required time (1 or 2 min.)	Alarm will be generated & message will displayed on MMI		
Too long time pre pressure	Set, TLT for pre pressure set point less than actual required time (1 or 2 min.)	Alarm indication will be ON till it is acknowledged.		
Too long time for post pressure	Set, TLT for post pressure set point less than actual required time (1 or 2 min.)	Alarm indication will be ON till it is acknowledged.		
Vacuum pump trip	Trip the pump manually by the override provided on overload relay	Alarm will generate & message will be displayed on MMI.		
Too long time for heat up	Set, TLT for heat up set parameter lesser than actual required time (1 or 2 min.)	Alarm will be generated & message will be displayed on MMI		
Too long time for vacuum break	If the time required for breaking vacuum exceeds the set time in PLC	Alarm will be generated & message will be displayed on MMI till it acknowledge.		
Door precondition	During the process, put off compressed air utility supply.	Alarm will generate & message will be		

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
fail		displayed on MMI		
Process end	When process is ends	Alarm indication will be ON till it is acknowledged.		
Chamber condensate temperature sensor 1 fail	If temperature sensor 1 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor 1 in controlling		
Chamber condensate temperature sensor 2 fail	If temperature sensor 2 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor 2 in controlling		
Chamber condensate temperature sensor 3 fail	If temperature sensor 3 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor 3 in controlling		
Chamber condensate temperature sensor 4 fail	If temperature sensor 4 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor		

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
		4 in controlling		
Chamber condensate temperature sensor 5 fail	If temperature sensor 5 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor 5 in controlling		
Chamber pressure sensor (Transmitter) fail.	If the chamber pressure drops below -0.99 bar & goes above 2-9	Alarm indication will be ON & process will not halt (alarm to be rectified or process to be aborted manually in fail safe condition.		

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8.6 Safety Valve:

Safety	Method	Required	Observation	Observed By (Engineering) Sign/Date
Working of safety valves.	Increase chamber pressure by 15% of the working pressure.	Chamber steam will blow off through safety valve		
	Increase jacket pressure by 15% of the working pressure.	Jacket steam will blow off through safety valve		

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8.7 Parameter Settings For Chamber Vacuum Leak Test (Cold):

Parameter	Purpose	Set value	Observations	Observed By (Engineering) Sign/Date
Pre Vacuum	To create maximum vacuum	-0.700 bar.		
Delay before hold	To stabilize vacuum level after shutting off valve & pump	3 min.		
Vacuum hold time	To check the leakage during hold period	10 min.		
Acceptable Leakage	Maximum acceptable limit	0.013 bar.		
Process End Pressure	To end the process & open the door.	-0.030 bar.		

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8.8 Parameter Settings for Chamber Vacuum Leak Test (Hot):

Parameter	Purpose	Set value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	-0.600 bar		
Pre pressure	To break the vacuum with steam	0.500 bar		
No. of pre pulses	To repeat the vacuum pressure pulses	3 nos		
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 bar		
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 bar		
No. of pulses	To achieve effective heat distribution	5 nos		
Pre pressure down final	--	0.600 bar		
Small valve set point	--	120.0 °C		
Ster. Hold temp.	Sterilization	121.4°C g c		
Ster. Hold time	To hold the sterilization period as per the set time	10 min		
Temp. Control band	To control max & min level of temperature during sterilization period	0.2°C		
Overshoot temperature	To alarm the excess temperature in the chamber during sterilization hold period.	124.0 ° C		
Sterilization stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period.	120.9°C		

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Parameter	Purpose	Set value	Observations	Observed By (Engineering) Sign/Date
Sterilization reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5 °C		
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 bar		
Post vacuum	To achieve set level of vacuum	-0.600 bar		
Vacuum drying hold	--	5 min		
Delay before hold		3 min		
Vacuum hold time	To dry the load.	10 min		
Acceptable leakage	--	0.013 bar		
Process end pressure	To end the process & open the door	-0.030 bar		

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8.9 Parameter Settings For warm up cycle

S.No.	Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
1.	Pre vacuum	To create vacuum for air removal	-0.500 bar		
2.	Warm up Hold Temp	--	121.4 °C		
3.	Warm up Hold	--	10 min		
4.	Temp. Control band	To control max & min level of temperature during sterilization period	0.2°C		
5.	Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 bar		
6.	Post vacuum	To achieve set level of vacuum	-0.400		
7.	Post vacuum hold time	To dry the load.	2 min		
8.	Process end pressure	To end the process & allow to unload the material	-0.040 bar		

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8.10 Parameter Settings for Bowie Dick test:

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	-0.600 bar		
Pre pressure	To break the vacuum with steam	0.500 bar		
No. of pre pulses	To repeat the vacuum pressure pulses	3 Nos.		
Pre pressure up	For pressure pulses to improve heat distribution	0.700 bar		
Pre pressure down	For pressure pulses to improve heat distribution	0.300 bar		
Pre pressure down final	--	0.600 bar		
Small valve sp	--	120.0 °C		
Ster. Hold temp.	Sterilization	121.4°C		
Ster. Hold time	To hold the sterilization period as per the set time	660 sec		
Temperature control band	To control max. & min. level of temperature during sterilization period	0.2 ° C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC		
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.9ºC		
Ster. Reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.5ºC		
Process end pressure	To end the process & allow to unload the material	0.040 Bar		

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8.11 Parameter Settings For Standard Process:

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	0.000 Bar		
Pre pressure	To break the vacuum with steam	0.000 Bar		
No. of pre pulses	To repeat the vacuum pressure pulses	0 Nos.		
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar		
No. of pulses	To achieve effective heat distribution	5 Nos.		
Pre pressure down final	--	0.600 Bar		
Small valve set point	--	120.0 ºC		
Ster. Hold temp.	Sterilization	121.4ºC		
Ster. Hold time	To hold the sterilization period as per the set time	30 Min		
Temp. Control band	To control max & min level of temperature during sterilization period	0.2ºC		
Overshoot Temperature	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0 °C		
Sterilization Stop Temperature	To stop the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.9 °C		
Sterilization Reset Temperature	To reset the sterilization hold time incase the chamber temperature falls below this value during	120.5 °C		
Process end pressure	To End the process & allow to unload the material	0.040 Bar		

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8.12 Parameter settings for HPHV Process I :

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	-0.600 Bar		
Pre pressure	To break the vacuum with steam	0.500 Bar		
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.		
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar		
No. of pulses	To achieve effective heat distribution	5 Nos.		
Pre pressure down final	--	0.600 Bar		
Small valve set point	--	120.0ºC		
Ster. Hold temp.	Sterilization	121.4ºC		
Ster. Hold time	To hold the sterilization period as per the set time	30 Min		
Temp. Control band	To control max & min level of temperature during sterilization period	0.2 ° C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC		
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC		
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar		
Post vacuum	To achieve set level of vacuum	-0.500 Bar		
Post vacuum	To dry the load.	5 Min		

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
hold time				
Post pressure	To break the vacuum by filtered air	-0.100 Bar		
No. Of post pulses	To achieve effective drying	3 Nos		
Process end pressure	To end the process & allow to unload the material	-0.040 Bar		

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8.13 Parameter settings for HPHV Process II :

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	-0.600 Bar		
Pre pressure	To break the vacuum with steam	0.500 Bar		
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.		
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar		
No. of pulses	To achieve effective heat distribution	5 Nos.		
Pre pressure down final	--	0.600 Bar		
Small valve set point	--	120.0ºC		
Ster. Hold temp.	Sterilization	121.4ºC		
Ster. Hold time	To hold the sterilization period as per the set time	30 Min		
Temp. Control band	To control max & min level of temperature during sterilization period	0.2 ° C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC		
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC		
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar		
Post vacuum	To achieve set level of vacuum	-0.500 Bar		
Post vacuum	To dry the load.	5 Min		

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Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
hold time				
Post pressure	To break the vacuum by filtered air	-0.100 Bar		
No. Of post pulses	To achieve effective drying	2 Nos		
Process end pressure	To end the process & allow to unload the material	-0.040 Bar		

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Sign/Date: ……

8.14 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

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Sign/Date: ……

8.15 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the OFF button Pressed in, Try to cause movement of an Operating function.	The Equipment will be inoperative.		

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Sign/Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Health Technical Memorandum 2010 Sterilization Part 3:Validation and verification
- Operational qualification from party

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of Draft SOPs.
- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

No.	:	Number
cGMP	:	Current Good Manufacturing Practices
ID.	:	Identification
Ltrs	:	Liters
HPHV	:	High pressure high vacuum
SOP	:	Standard operating procedure
°C	:	Degree centigrade
Min.	:	Minute

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			