



**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
CIP-SIP MODULE  
CAPACITY:500 LITER**

<b>EQUIPMENT ID No.</b>	
<b>LOCATION</b>	<b>CIP/SIP ROOM</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDED REPORT NO.</b>	<b>NIL</b>



**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

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# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

### 1.0 REPORT PRE APPROVAL:

#### PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

#### REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

#### APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

#### AUTHORIZED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**2.0 OBJECTIVE:**

The objective of this validation report is to establish documented evidence that the CIP-SIP Module is suitable for cleaning and sterilization of the manufacturing vessels & Holding vessels along with the associated product line with filter housings and filters can repeatedly and reproducibly be able to sterilize effectively the subjected system within the established acceptance criteria limits.

**3.0 SCOPE:**

The scope of this particular validation report is applicable to the CIP-SIP of manufacturing vessels and Holding vessels, associated product line, installed in the CIP/SIP area.



**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, authorization and Compilation of Performance qualification Reports</li><li>• To provide analytical support for validation activity.</li></ul>
<b>Quality Control</b>	<ul style="list-style-type: none"><li>• Analytical Support (Microbiological Testing / Analysis)</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Performance Qualification Report.</li><li>• To co-ordinate and support Performance qualification Activity.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Performance Qualification Report.</li><li>• To co-ordinate and support Validation Activity.</li><li>• Responsible for Trouble shooting during execution (If Occurs).</li></ul>
<b>External Qualification Agency if Applicable)</b>	<ul style="list-style-type: none"><li>• Performance of qualification activity as per protocol</li></ul>



**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	CIP/SIP Module
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Capacity</b>	250 Ltr.
<b>Place of Installation</b>	CIP/SIP Room

**6.0 PRE – QUALIFICATION REQUIREMENTS:**

**6.1 Verification of Documents:**

<b>S. No.</b>	<b>DOCUMENT NAME</b>	<b>DOCUMENT / SOP NO.</b>	<b>COMPLETED (YES/NO)</b>	<b>CHECKED BY (QA) SIGN/DATE</b>
1.	Executed & approved DQ Protocol Cum Report			
2.	Executed & approved IQ Protocol Cum Report			
3.	Executed & approved OQ Protocol Cum Report			
4.	Approved PQ Protocol			
5.	SOP for Operating, Cleaning of the CIP/SIP Module			
6.	SOP for Preventive Maintenance of the CIP/SIP Module			

**Inference:**

.....  
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.....

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



**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**7.0 TESTS AND CHECKS:**

**7.2 TEST FOR EFFICIENCY OF WASHING CYCLE FOR MANUFACTURING TANK  
( 1000 Ltr.) & CONNECTED LOOP:**

Date of Test		Equipment Name	
Block		Equipment ID	
Area		Batch Size	
Tank capacity		Equipment Make	
B.No. of NaOH			

**CIP Cycle with 5% NaOH**

Parameter	Result
pH	
Conductivity	

**CIP Cycle with 10% NaOH**

Parameter	Result
pH	
Conductivity	

**CIP Cycle with 15% NaOH**

Parameter	Result
pH	
Conductivity	

**ACCEPTANCE CRITERIA:**

S.No.	Critical variables	Acceptance criteria
1.	pH	5.0 to 7.
2.	Conductivity	NMT 1.3 $\mu$ s



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**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**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 CIP-SIP MODULE (250 LITER)**

**7.3 TEST FOR EFFICIENCY OF WASHING CYCLE FOR MANUFACTURING TANK (2000 Ltr.)  
& CONNECTED LOOP:**

<b>Date of Test</b>		<b>Equipment Name</b>	
<b>Block</b>		<b>Equipment ID</b>	
<b>Area</b>		<b>Batch Size</b>	
<b>Tank capacity</b>		<b>Equipment Make</b>	
<b>B.No. of NaOH</b>			

**CIP Cycle with 5% NaOH**

<b>Parameter</b>	<b>Result</b>
<b>pH</b>	
<b>Conductivity</b>	

**CIP Cycle with 10% NaOH**

<b>Parameter</b>	<b>Result</b>
<b>pH</b>	
<b>Conductivity</b>	

**CIP Cycle with 15% NaOH**

<b>Parameter</b>	<b>Result</b>
<b>pH</b>	
<b>Conductivity</b>	

**ACCEPTANCE CRITERIA:**

<b>Sr. NO.</b>	<b>Critical variables</b>	<b>Acceptance criteria</b>
<b>01</b>	pH	5.0 to 7.
<b>02</b>	Conductivity	NMT 1.3 $\mu$ s



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**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**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 CIP-SIP MODULE (250 LITER)**

**7.4 TEST FOR EFFICIENCY OF WASHING CYCLE FOR HOLDING TANK( 2000 Ltr.) & CONNECTED LOOP:**

<b>Date of Test</b>		<b>Equipment Name</b>	
<b>Block</b>		<b>Equipment ID</b>	
<b>Area</b>		<b>Batch Size</b>	
<b>Tank capacity</b>		<b>Make OF Manufacturing Vessel</b>	
<b>B.No. of NaOH</b>			

**CIP Cycle with 5% NaOH**

<b>Parameter</b>	<b>Result</b>
<b>pH</b>	
<b>Conductivity</b>	

**CIP Cycle with 10% NaOH**

<b>Parameter</b>	<b>Result</b>
<b>pH</b>	
<b>Conductivity</b>	

**CIP Cycle with 15% NaOH**

<b>Parameter</b>	<b>Result</b>
<b>pH</b>	
<b>Conductivity</b>	

**ACCEPTANCE CRITERIA:**

<b>Sr. NO.</b>	<b>Critical variables</b>	<b>Acceptance criteria</b>
<b>01</b>	pH	5.0 to 7.
<b>02</b>	Conductivity	NMT 1.3 $\mu$ s



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**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**Checked By**  
**(Production)**  
**Sign/Date: .....**

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

**Inference:**

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



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

### 7.5 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK (1000 Ltr.) & CONNECTED LOOP:

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

Name of Cycle	Heat Distribution Study		
Date of test		Equipment Make	
Equipment Name		Equipment ID	
Capacity of vessel		Equipment Location	

Set Parameters:	Acceptance Criteria	Observation
Leak test Pressure	1.50 bar	
Stabilization time	2 Minute	
Leak Test Time	3 minute	
Leak Rate	0.20 bar	
Purging time	030 Second	
Sterilization Pressure	1.50 Bar	
Pressure Dead Band	0.02 bar	
Pulsation temperature	115.0°C	
Sterilization Temperature	122.0 °C	
Heating ON Temperature	123.5 °C	
Heating OFF Temperature	124.0°C	
Sterilization Hold Time	30 Minute	
Sterilization Fail Temperature	120.5°C	
Overshoot Temperature	127 °C	
Drain Time	2 Minute	
Cooling Temperature	80 °C	

Checked By  
(Production)  
Sign/Date: .....

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

Inference:.....  
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.....

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



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

OBSERVATION	Cycle-1		Cycle -2		Cycle-3	
	Internal	External	Internal	External	Internal	External
Cycle Start Date						
Cycle Start Time						
Cycle End Date						
Cycle End Time						
Sterilization Temperature start Time						
Sterilization Temperature end Time						
Total Hold time						
Cold Spot Location						

**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 CIP-SIP MODULE (250 LITER)**

**7.5.1 F<sub>0</sub> CALCULATION**

**(a) (a) Numerical F<sub>0</sub> Value:**

Calculate numerical F<sub>0</sub> value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z}$$

F<sub>0</sub>=

**Where,**

dt : Time interval between successive temperature measurements (in min).

T : Observed temperature at that particular time (as per the actual temperatures recorded)

Z = change in the heat resistance of *Geobacillus stearothermophilus* spores as temperature is changed (10<sup>0</sup>C or as mentioned in COA).

**(b) F<sub>0</sub> Value for Biological Indicators:**

The biological F<sub>0</sub> value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B)$$

F<sub>0</sub>=

**Where,**

D<sub>121</sub> : D value of the biological indicator at 121<sup>0</sup>C

A : Experimental Biological indicator concentration or spore population

B : Desired level of sterility (SAL- 10<sup>-6</sup>)

**(c) Desired Spore log reduction:**

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

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}}$$

SLR<sub>desired</sub> =

**Where,**

A : Experimental population of Biological Indicator

SLR<sub>desired</sub> : Desired level of sterility (10<sup>-6</sup>)

**(d) Actual Spore log reduction**

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121}$$

SLR<sub>Actual</sub> =

**Where,**

F<sub>0</sub> : Minimum Calculated F<sub>0</sub> value

D<sub>121</sub> : D value of the Biological Indicator at 121<sup>0</sup>C



**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**7.5.2 OBSERVATIONS:**

Cycle : 01

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual	

**Checked By**  
**(Production)**  
Sign/Date: .....  
**Inference:**.....

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

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





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QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

Cycle : 02

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological 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: .....



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

**Cycle : 03**

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological 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 CIP-SIP MODULE (250 LITER)**

**7.6 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK (2000 Ltr.) & CONNECTED LOOP:**

<b>Test Instrument Name</b>		<b>Model No</b>		<b>Calibration done Date</b>	
<b>Sensors type &amp; Qty.</b>		<b>Make</b>		<b>Calibration due Date</b>	
<b>Name of Cycle</b>			<b>Heat Distribution Study</b>		
<b>Date of test</b>		<b>Equipment Make</b>			
<b>Equipment Name</b>		<b>Equipment ID</b>			
<b>Capacity of vessel</b>		<b>Equipment Location</b>			
<b>Set Parameters:</b>		<b>Acceptance Criteria</b>		<b>Observation</b>	
<b>Leak test Pressure</b>		<b>1.50 bar</b>			
<b>Stabilization time</b>		<b>2 Minute</b>			
<b>Leak Test Time</b>		<b>3 minute</b>			
<b>Leak Rate</b>		<b>0.20 bar</b>			
<b>Purging time</b>		<b>30 Second</b>			
<b>Sterilization Pressure</b>		<b>1.50 Bar</b>			
<b>Pressure Dead Band</b>		<b>0.02 bar</b>			
<b>Pulsation temperature</b>		<b>115.0°C</b>			
<b>Sterilization Temperature</b>		<b>122.0 °C</b>			
<b>Heating ON Temperature</b>		<b>123.5 °C</b>			
<b>Heating OFF Temperature</b>		<b>124.0°C</b>			
<b>Sterilization Hold Time</b>		<b>30 Minute</b>			
<b>Sterilization Fail Temperature</b>		<b>120.5°C</b>			
<b>Overshoot Temperature</b>		<b>127 °C</b>			
<b>Drain Time</b>		<b>2 Minute</b>			
<b>Cooling Temperature</b>		<b>80 °C</b>			

**Checked By**  
**(Production)**  
**Sign/Date: .....**

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

**Inference:.....**  
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.....

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



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

OBSERVATION	Cycle-1		Cycle -2		Cycle-3	
	Internal	External	Internal	External	Internal	External
Cycle Start Date						
Cycle Start Time						
Cycle End Date						
Cycle End Time						
Sterilization Temperature start Time						
Sterilization Temperature end Time						
Total Hold time						
Cold Spot Location						

**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 CIP-SIP MODULE (250 LITER)**

**7.6.1 F<sub>0</sub> CALCULATION**

**(a) (a) Numerical F<sub>0</sub> Value:**

Calculate numerical F<sub>0</sub> value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z}$$

F<sub>0</sub>=

**Where,**

dt : Time interval between successive temperature measurements (in min).

T : Observed temperature at that particular time (as per the actual temperatures recorded)

Z = change in the heat resistance of *Geobacillus stearothermophilus* spores as temperature is changed (10<sup>0</sup>C or as mentioned in COA).

**(b) F<sub>0</sub> Value for Biological Indicators:**

The biological F<sub>0</sub> value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B)$$

F<sub>0</sub>=

**Where,**

D<sub>121</sub> : D value of the biological indicator at 121<sup>0</sup>C

A : Experimental Biological indicator concentration or spore population

B : Desired level of sterility (SAL- 10<sup>-6</sup>)

**(c) Desired Spore log reduction:**

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

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}}$$

SLR<sub>desired</sub> =

**Where,**

A : Experimental population of Biological Indicator

SLR<sub>desired</sub> : Desired level of sterility (10<sup>-6</sup>)

**(d) Actual Spore log reduction**

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121}$$

SLR<sub>Actual</sub> =

**Where,**

F<sub>0</sub> : Minimum Calculated F<sub>0</sub> value

D<sub>121</sub> : D value of the Biological Indicator at 121<sup>0</sup>C



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**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**7.6.2 OBSERVATIONS:**

Cycle : 01

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological 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:** .....



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

Cycle : 02

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological 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: .....



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

Cycle : 03

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological 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: .....





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## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

### 7.7 HEAT DISTRIBUTION STUDY FOR HOLDING TANK (2000 Ltr.) & CONNECTED LOOP:

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	
Name of Cycle		Heat Distribution Study			
Date of test		Equipment Make			
Equipment Name		Equipment ID			
Capacity of vessel		Equipment Location			
<b>Set Parameters:</b>		<b>Acceptance Criteria</b>		<b>Observation</b>	
Leak test Pressure		1.50 bar			
Stabilization time		2 Minute			
Leak Test Time		3 minute			
Leak Rate		0.20 bar			
Purging time		030 Second			
Sterilization Pressure		1.50 Bar			
Pressure Dead Band		0.02 bar			
Pulsation temperature		115.0°C			
Sterilization Temperature		122.0 °C			
Heating ON Temperature		123.5 °C			
Heating OFF Temperature		124.0°C			
Sterilization Hold Time		30 Minute			
Sterilization Fail Temperature		120.5°C			
Overshoot Temperature		127 °C			
Drain Time		2 Minute			
Cooling Temperature		80 °C			

Checked By  
(Production)  
Sign/Date: .....

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

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



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

OBSERVATION	Cycle-1		Cycle -2		Cycle-3	
	Internal	External	Internal	External	Internal	External
Cycle Start Date						
Cycle Start Time						
Cycle End Date						
Cycle End Time						
Sterilization Temperature start Time						
Sterilization Temperature end Time						
Total Hold time						
Cold Spot Location						

**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 CIP-SIP MODULE (250 LITER)**

**7.7.1 F<sub>0</sub> CALCULATION**

**(a) (a) Numerical F<sub>0</sub> Value:**

Calculate numerical F<sub>0</sub> value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z}$$

F<sub>0</sub> =

**Where,**

- dt : Time interval between successive temperature measurements (in min).  
T : Observed temperature at that particular time (as per the actual temperatures recorded)

Z = change in the heat resistance of *Geobacillus stearothermophilus* spores as temperature is changed (10<sup>0</sup>C or as mentioned in COA).

**(b) F<sub>0</sub> Value for Biological Indicators:**

The biological F<sub>0</sub> value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B)$$

F<sub>0</sub> =

**Where,**

- D<sub>121</sub> : D value of the biological indicator at 121<sup>0</sup>C  
A : Experimental Biological indicator concentration or spore population  
B : Desired level of sterility (SAL- 10<sup>-6</sup>)

**(c) Desired Spore log reduction:**

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

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}}$$

SLR<sub>desired</sub> =

**Where,**

- A : Experimental population of Biological Indicator  
SLR<sub>desired</sub> : Desired level of sterility (10<sup>-6</sup>)

**(d) Actual Spore log reduction**

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121}$$

SLR<sub>Actual</sub> =

**Where,**

- F<sub>0</sub> : Minimum Calculated F<sub>0</sub> value  
D<sub>121</sub> : D value of the Biological Indicator at 121<sup>0</sup>C



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**7.7.2 OBSERVATIONS:**

Cycle : 01

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological 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: .....



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## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

Cycle : 02

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological 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: .....



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QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

Cycle : 03

Probe No	Sterilizing Temperature (°c)		F <sub>0</sub> Value		Spore Log Reduction		Biological 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 CIP-SIP MODULE (250 LITER)**

**8.0 CHECKLIST OF ALL TESTS AND CHECKS:**

TESTS OR CHECKS	EXECUTED [Y/N]	REMARK
Test for Efficiency of washing Cycle for Mixing tank & Connected Loop		
Test for Efficiency of washing Cycle for Mixing tank & Connected Loop		
Test for Efficiency of washing Cycle for Holding tank & Connected Loop		
Heat distribution study for Manufacturing Tank (1000 Ltr.) & Connected Loop		
Heat distribution study for Manufacturing Tank (2000 Ltr.) & Connected Loop		
Heat Distribution Study For Holding Tank (2000 ltr. )& Connected Loop		
Biological challenge Study		

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

**Inference:**

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



**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**9.0 DOCUMENTS TO BE ATTACHED:**

- Raw data of Chemical Analysis.
- Calibration Certificates for Conductivity Meter.
- Calibration Certificates for pH Meter.

**10.0 NON COMPLIANCE:**

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**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**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 CIP-SIP MODULE (250 LITER)**

**16.0 ABBREVIATIONS:**

QA	:	Quality Assurance
QC	:	Quality Control
No.	:	Number
Ltd.	:	Limited
ID No.	:	Identification Number
ml	:	Milliliter
CIP	:	Clean In Place
SIP	:	Sterilization in Place
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
SLR	:	Spore log reduction
SAL	:	Sterility assurance level
%	:	Percentage
°C	:	Centigrade



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QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)**

**17.0 REPORT POST APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			