PERFORMANCE QUALIFICATION REPORT FOR INDUCTION SEALING MACHINE

EQUIPMENT ID No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR INDUCTION SEALING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR INDUCTION SEALING MACHINE	PROTOCOL No.:

1.0 PROTOCOL 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)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing as per the parameter defined in Performance Qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

This Protocol is applicable for performance qualification of Induction Sealing Machine installed in Dry Powder filling area.

4.0 RESPONSIBILITY:

The Qualification team, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification Protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.
Quality Control	• Review of Performance Qualification report. • Approval of report post approval.

5.0 EQUIPMENT DETAILS:

Equipment Name	Induction Sealing Machine
Equipment ID.	
Manufacturer's Name	Electronic Device
Supplier's Name	Electronic Device
Location of Installation	

6.0 SYSTEM DESCRIPTION:

The closure is supplied to the bottler with foil liner already inserted. Although there are various liners to choose from, a typical induction liner is multi-layered. The top layer is a paper pulp that is generally spot-glued to the cap. The next layer is wax that is used to bond a layer of aluminum foil to the pulp. The bottom layer is a polymer film laminated to the foil. After the cap or closure is applied, the container passes under an induction coil, which emits an oscillating electromagnetic field. As the container passes under the induction coil (sealing head) the conductive aluminum foil liner begins to heat. The heat melts the wax, which is absorbed into the pulp backing and releases the foil from the cap. The polymer film also heats and flows onto the lip of the container. When cooled, the polymer creates a bond with the container resulting in a hermetically sealed product. Neither the container nor its contents are affected, and this all happens in a matter of seconds.

7.0 REASON FOR QUALIFICATION:

After completion of the Operational Qualification of the equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Dry Powder Injection Area.

9.0 FREQUENCY OF QUALIFICATION:

- Once in two year time period.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE-QUALIFICATION REQUIREMENTS:

10.1 TRAINING: Training shall be given to the concerned persons and details recorded into the **Annexure-I.**

10.2 SYSTEM PRE-REQUISITES:

Verify that the DQ / IQ / OQ of the Induction Sealing machine have been executed and approved.

Verify that the SOP for Operating, Cleaning and Preventive Maintenance of the Induction Sealing machine has been prepared.

S.No.	DESCRIPTION OF PRE-REQUISITE	COMPLETED (YES / NO)	CHECKED BY ENGINEERING SIGN / DATE	VERIFIED BY QA SIGN / DATE
1. 2. 3.	Verify that the DQ / IQ / OQ of the Induction Sealing machine has been executed and approved. DQ Protocol Document No.: IQ Protocol Document No.: OQ Protocol Document No.:			
4.	SOP of “Operation and Cleaning of Induction Sealing machine”			

11.0 TESTS & CHECKS:

11.1 CONVEYER SPEED TEST:

Objective:

The objective of the test to determine the effect of Conveyer speed on product quality.

Scope:

The Scope of this test limited to the Dry Powder Filling Area.

Procedure:

- Switch on the conveyer Belt Machine.
- Operate the machine as per respective SOP.
- Set the Minimum, Standard and Maximum speed of Conveyer Belt.
- Put the Bottles on the conveyer belt.
- Check the effect of speed on bottle.
- The result record into the **Annexure-I.**

Acceptance criteria: The conveyer belt should not affect the product quality.

11.2 LEAK TEST:

Objective:

The objective of the test to determine the leakage in bottle.

Scope:

The Scope of this test limited to the Dry Powder Filling Area.

Test Instrument:

Leak Test Apparatus

PROCEDURE:

- The test shall be performing at the preset speed.
- The test shall be perform on 3 consecutive batches.
- Switch "ON" the machine & operate as per SOP.
- Set the Temperature at 90°C -100°C.
- Collect the 10 bottles continuous initial, middle and Final and each variability.
- Perform leak test at specified in BPR.
- Record the data in **Annexure-III**.

ACCEPTANCE CRITERIA:

Leakage should not be observed.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

The following table lists the number of tests / samples to be carried out & comments on the sample record sheet.

TESTS OR CHECKS	EXECUTED [Y/N]	COMMENT
CONVEYER SPEED TEST		
LEAK TEST		

13.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents

14.0 NON COMPLIANCE:

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15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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16.0 CHANGE CONTROL, IF ANY:

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17.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)

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18.0 CONCLUSION:

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19.0 RECOMMENDATION:

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20.0 ABBREVIATIONS:

Sr.	:	Senior
No.	:	Number
gm	:	gram
BSS	:	British Standard Sieve
BMR	:	Batch Manufacturing Record
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
GMP	:	Good Manufacturing Practices
SOP	:	Standard Operating Procedure
ICS	:	Induction Sealing Machine
^{o}C	:	Degree Centigrade
mm	:	Millimeter
Amp.	:	Amper
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification

21.0 ANNEXURE:

S.No.	Title
1.	Training Record
2.	Result of Conveyer Speed Test
3.	Result of Leak Test

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR INDUCTION SEALING MACHINE	PROTOCOL No.:

Annexure-I

(Training Detail)

S. No.	Name	Department	Sign.	Duration	Remarks

Trainer Name:

Date & Sign:

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR INDUCTION SEALING MACHINE	PROTOCOL No.:

Annexure-II

(Result of Conveyer Speed Test)

Product Name: **Batch No.:**

Manufacturing date: **Expiry Date:**

At Minimum Speed (30 feet/min):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

At Standard Speed (40 feet/min):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

At Maximum Speed (50 feet/min):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

Checked By
Production
Sign / Date

Verified By
Quality Assurance
Sign / Date

Inference:……..……

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Reviewed By:_____
Manager QA
Sign / Date

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR INDUCTION SEALING MACHINE	PROTOCOL No.:

Annexure-III

(Result of Leak Test)

Product Name: **Batch No.:**

Manufacturing date: **Expiry Date:**

At Minimum Temperature (90°C):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

At Standard Temperature (95°C):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

At Maximum Temperature (100°C):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

Checked By
Production
Sign / Date

Verified By
Quality Assurance
Sign / Date

Inference:……..……

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Reviewed By:_____
Manager QA
Sign / Date

22.0 REPORT POST APPROVAL

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			