PERFORMANCE QUALIFICATION PROTOCOL FOR INDUCTION SEALING MACHINE

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

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL 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 Packing Hall. The equipment is to be used for Sealing of bottle.

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	
Supplier's Name	
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

The closure is supplied to the bottle 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:

- New equipment installed in Packing Hall.
- After completion of the Operation 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:

Packing Hall.

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 and attached in qualification Report.

10.2 SOP for the **"Operation and Cleaning of the Induction sealing machine".**

11.0 TESTS & CHECKS:

11.1 Objective :

To establish the **Induction sealing of 3 Layer Bottles caps & 7 Layer Bottles caps** for smooth running of the Induction Cap Sealing Machine based on the following parameters:

- Conveyor speed
- % Power
- Induction head height from bottle cap

11.2 Test Requirements:

3 Layer HDPE Bottles cap & 7 layer Bottles Caps with induction seal.

11.3 Procedure: As per respective Standard Operating Procedure.

11.4 Induction Sealing Cap Machine process critical Parameters :

The parameters listed below are critical to a robust, repeatable induction sealing process. The Critical parameters that are listed as "Constant" will remain unchanged during all of the Qualification runs. The critical parameters listed as "Variable" can be changed within the range of qualified settings provided. Changes made outside of the qualified range will require consent from Pack Dev and QA prior to implementation. The table below is for reference purposes only. The final settings identified during the qualification will be recorded and documented in the final report.

Test Parameter	Low	Centerline	High
Conveyer Speed	(12 Hz on VFD)	(15 Hz on VFD)	(20 Hz on VFD)
% Power	75	80	85
Induction Head Height (mm)	3	5	7

11.5 Induction Sealing Machine running conditions :

RUN #	INDUCTION HEAD HEIGHT	% POWER	CONVEYER SPEED
1	Low (3 mm)	Low (75%)	Centerline (12 Hz on VFD)
2	High (7 mm)	High (85%)	Centerline (20 Hz on VFD)
3	Centerline (5 mm)	Centerline (80%)	Low (15 Hz on VFD)

11.6 Samples Pull Table :

SEAL INTEGRITY / VISUAL INSPECTION		
RUN 1	**RUN 2**	**RUN 3**
10 Bottles	10 Bottles	10 Bottles

12.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan
- Schedule M: "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2: Good Manufacturing Practices and Inspection.

13.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

14.0 NON COMPLIANCE:

All the Non compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.

- The Head QA shall study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

16.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA shall study the impact of change. If change is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

17.0 ABBREVIATIONS:

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
RH	:	Relative Humidity
^{o}C	:	Degree Centigrade
mm	:	Millimeter
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
Pvt.	:	Private
Ltd.	:	Limited