OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR INDUCTION SEALING MACHINE

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

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

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

1.0 PRE 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)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set of Acceptance Criteria and comply with relevant GMP Requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the Operational features of Induction Sealing Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Equipment, Cleaning Procedure, start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The Protocol covers all the aspects of Operation Qualification for Induction Sealing Machine.
- This Protocol defines the methods and documents to be used to qualify the Induction Sealing Machine for OQ.
- Successful completion of this Protocol will verify that the Induction Sealing Machine meets all acceptance criteria and is ready for Performance Qualification.

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 Operation Qualification Protocol. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review of Operation Qualification Protocol. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol.
Engineering	• Review & Pre Approval of Operational Qualification Protocol. • Co-ordination, Execution and technical support in Induction Sealing Machine Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution).

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 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 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design and Installation qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

7.2 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 IQ Protocol cum report.

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 THE DOCUMENT:

S.No.	Document name	Completed (Yes/No)	Checked by Engineering Sign/Date	Verified By QA Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP for Operation & Cleaning of Induction Sealing Machine			
4.	SOP for Preventive Maintenance of Induction Sealing Machine			

Checked By
Production
Sign/Date:……

Verified By
Quality Assurance
Sign/Date:……

Inference:……..

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Reviewed By
Manager QA
Sign/Date:…….

8.2 TEST EQUIPMENT CALIBRATION:

Instruments name	Instrument ID	Calibration on	Due on	Observed by Sign/Date

Checked By
Production
Sign/Date:……

Verified By
Quality Assurance
Sign/Date:……

Inference:……..

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Reviewed By
Manager QA
Sign/Date:…….

8.3 OPERATIONAL AND FUNCTIONAL CHECKS:

Operate the Induction Sealing machine as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired

Operation	Acceptance criteria	Observation
Check correct working of Machine	The machine should be operational	
Check working of and pressure gauges	Displayed pressures should be within the set limits.	
Removal of change parts and product changeover	As per changeover diagram. It should not take more than1 hour	
Removal of product contact parts and cleaning	It should not take more than 1 hour.	
To Check the temperature: When temperature High and Low	When temperatures fluctuate from the specified limit machine should not seal the cap and alarm also indicates.	
To check over Voltage Trip	It indicates that a voltage surge or other situation has caused an over voltage condition, the inverter should stop in safe mode.	
To check Loose cap fault	When the Cap not fully seated on the container the alarm should indicate and reject container.	
To check the missing foil fault	When the container pass under the sealing coil that did not have a liner installed should not sealed and hooter also indicate	

Checked By
Production
Sign/Date:……

Verified By
Quality Assurance
Sign/Date:……

Inference:……..

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Reviewed By
Manager QA
Sign/Date:……..

8.4 POWER FAILURE VERIFICATION:

ITEM	RESULTS	OBSERVATION	OBSERVED BY ENGINEERING SIGN / DATE
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions		

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
Sign / Date:……

Inference:……..

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Reviewed By
Manager QA
Sign / Date:…….

9.0 REFERENCES:

- 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates
- 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 Practice
GMP	:	Good Manufacturing Practice
WHO	:	World Health Organization
P & ID	:	Piping and Instrumentation diagram
RH	:	Relative Humidity
^{0}C	:	Degree Centigrade
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
PU	:	Polyurethane
AC	:	Alternating Current
mm	:	Millimetre
HP	:	Horse Power
RPM	:	Revolution Per Minute
Amp.	:	Ampere
SS	:	Stainless Steel
Hr.	:	Hour
MOC	:	Material of construction
FDA	:	Food and Drug Administration
EU	:	European Union

17.0 POST- 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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HEAD (QUALITY ASSURANCE)			