INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INDUCTION SEALING MACHINE

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

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

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PHARMA DEVILS	INSTALLATION 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 carry out the Installation Qualification of Induction Sealing Machine used in Production, "The process conforming that an item of equipment, or other system, as currently installed, meets its design qualification".
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with GMP practices.
- To prove that each Operation proceeds as per the Design Specification and the tolerances prescribed there in the document, are the same at utmost transparency.
- To ensure that there is sufficient information available to enable the equipment to operate and maintain safely, effectively and consistently.

3.0 SCOPE:

- The Protocol covers all aspects of Installation Qualification of Induction Sealing Machine used in Production.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as built drawing numbers of equipment drawing, P & ID and circuit diagram.

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 and Approval of the Installation Qualification Protocol. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Process.
Production	• Giving clearance to install the unit. • Execution of Installation Qualification activity. • Ensure that the equipment is installed as per protocol. • Review and Approval of Protocol cum report.
Engineering	• To co–ordinate and support Installation Qualification activity. • Calibration of Process instruments. • Ensure that the equipment is installed as per protocol. • Review and Approval of Protocol cum report.

5.0 EQUIPMENT DETAILS:

Equipment Name	Induction Sealing Machine
Equipment	
Manufacturer's Name	Electronic Device
Model	Sigma-II
Supplier's Name	Electronic Device
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 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.

7.1.1 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 IQ 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 GENERAL CHECKS AND LOCATION SUITABILITY:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Leveling	Should be properly balanced and Leveled		
Edges of parts	The Metal parts should be properly grounded without any sharp edges		
Welding of Joints	Welding of joints should be without any Welding Burrs		
Place of Installation	Packing Hall		
Room Condition	General working condition.		
Illumination in area	Above 300 Lux		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
Production
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date:……..

Inference:

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Reviewed By
Manager QA
Sign/Date:…….

8.2 EQUIPMENT VERIFICATION:

Installation Checks	Acceptance Criteria	Observation	Observed by Engineering Sign / date
Equipment	Induction Sealing machine		
Model	SIGMA-II Model.		
ELECTRICAL INSTALLATION:			
Electrical Supply	3 Phase Voltage- 230 V (± 6%) Frequency- 50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured		
All components in the panel are properly secured	Should be secured		
All terminals are tightened	Should be tightened		

Checked By
Production
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date:……..

Inference:

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Reviewed By
Manager QA
Sign/Date:…….

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

8.3 INSTALLATION VERIFICATION:

S.No.	VARIABLE	OBSERVATION
1.	Check the proper mechanical installation of Induction Sealing machine	
2.	Check the proper alignment of Induction Sealing machine.	
3.	Check the proper electrical installation of Induction Sealing machine	
4.	Check the proper Mechanical Safety of Induction Sealing machine	
5.	Check the proper service connection such as compressed air supply, and illumination of Induction Sealing machine	
6.	Check the parts are working properly	
7.	Check the equipment is free from any defects	
8.	Check the finishing of product contact parts	
9.	Check that all parts are getting lubricated	

Checked By
Production
Sign / Date:…….

Verified By
Quality Assurance
Sign / Date:……..

Inference:

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Reviewed By
Manager QA
Sign / Date:…….

8.4 VERIFICATION OF MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Observation
1.0	Machine shell	SS304	
2.0	Sealing Head	Cast Iron.	
3.0	Conveyer	AISI 316	
4.0	Motor (“Delta Electronics” Make,)	STD.	
5.0	Motor (“Delta Electronics” Make,)	STD.	
6.0	Proximity switch (NO)	STD	
7.0	Conveyer	AISI 316	
8.0	Control Panel	AISI 316	

Checked By
Production
Sign / Date:…….

Verified By
Quality Assurance
Sign / Date:……..

Inference:

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Reviewed By
Manager QA
Sign / Date:…….

8.5 SAFETY TESTING:

Item	Acceptance criteria	Observation	Observed by Engineering Sign/date
Well embedded equipment	For proper sifting		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors).		
Guards	Guards for all moving parts Should be provided For Motor safety		
Start On / Off switch: To stop the process immediately	Should be provided For equipment and operator safety		
MCB for electrical overload	Should be properly installed		

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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificates of MOC.
- Calibration certificates.

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
RH	:	Relative Humidity
^{o}C	:	Degree Centigrade
DQ	:	Design Qualification
mm	:	Millimetre
HP	:	Horse Power
RPM	:	Revolution per Minute
Amp.	:	Ampere
SS	:	Stainless Steel
Kg	:	Kilogram
Hr.	:	Hour
MOC	:	Material of construction
IQ	:	Installation Qualification
MCB	:	Miniature Circuit Breaker
V	:	Volts

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
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