DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR INDUCTION SEALING MACHINE

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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PHARMA DEVILS	DESIGN 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 prepare the Design Qualification document for Induction Sealing Machine on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process / Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Induction Sealing Machine with Sigma-II Model procured from Electronic Device.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

4.0 RESPONSIBILITY:

The Validation team, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Approval and Authorization of the Protocol cum Report. • Assist in the verification of Critical Process Parameters & Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters & Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution
Engineering	• Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Design Qualification Activity. • To assist in Verification of Critical Process Design Feature & Drawings as per the Specification. • Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures. • Details of utilities • Material of construction of all components • Brief Process Description • Safety Features and Alarms • Post Approval of Qualification Protocol cum report after Execution

5.0 BRIEF ABOUT EQUIPMENT:

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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specification document is provided to manufacturer for engineering equipment & Some critical variables to be met during designing the equipment.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: Line Speed	Conveyor Speed Should be facillate the easy and efficient as per product requirement i.e. 50 feet / minute	Process Requirement
Working: Working on Induction sealing Machine	Induction Sealing Machine should be facillate the easy & efficient working during the course of the Sealing operations.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Approved Design Requirement

7.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and GEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in the service area.	Approved Design Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

CRITICAL VARIABLES		ACCEPTANCE CRITERIA	REFERENCE
Equipment		Induction Sealing Machine	Electronic Device
Model No.		SIGMA-II	As Per Approved Design Requirement
Capacity		20 mm - 120 mm	As Per Approved Design Requirement
Dimensions of Machine		650 mm x 650 mm x 1650 mm	As Per Approved Design Requirement
Electrical Supply		3.0 HP	As Per Approved Design Requirement
Power Requirement		230+- 10% V AC, 10 Amps, Single Phase	As Per Approved Design Requirement
Height of Induction		As per Requirement of Product	As Per Approved Design Requirement
Motor	Make	Delta Electronics	As Per Approved Design Requirement
	Sr. No	…….	
	Volt	230	

7.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Machine shell	SS304
2.	Sealing Head	Cast Iron
3.	Conveyer	AISI 316
4.	Motor (“Delta Electronics” Make,)	STD.
5.	Motor (“Delta Electronics” Make,)	STD.
6.	Proximity switch (NO)	STD

7.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB should be provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts should be provided	Safety Requirement
Joints	Welding of joints should be Leaving without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling And Balancing	Equipment should be Properly balanced & leveled.	Safety Requirement
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided.	Safety Requirement
Noise Level	Below 80 db.	cGMP Requirement
Emergency Switch	Provided easy access position.	Safety Requirement

7.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Induction Sealing Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feed back from market (customers already using the equipment)	Process Requirement

Reference: **(1)** the equipment shall confirm to the specifications and requirement as specified in PO and URS
(2) Operating and service manual for Induction Sealing Machine.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Minutes of meeting held with the supplier, if any.
- Any other relevant documents

9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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10.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATION:

URS	:	User Requirement specification
DQ	:	Design Qualification
PO	:	Purchase Order
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
Ltd.	:	Limited
QA	:	Quality Assurance
Kg	:	Kilogram
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
Db	:	Decibel

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			