DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VIAL SEALING MACHINE

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

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VIAL SEALING MACHINE	PROTOCOL No.:

CONTENTS

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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 on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Vial Sealing Machine (Make: Aegis Pharma Tech)** for ……..
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

4.0 RESPONSIBILITY:

The Validation Group, 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, Review and Approval 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 Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➢ Details of utilities. ➢ Identification of components for calibration. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Post Approval of Qualification Protocol after Execution.

5.0 BRIEF EQUIPMENT DESCRIPTION:

The equipment is an automated means of cap sealing for different size of vial. The equipment has four head for the capping action. The filled vials from the vial filling machine are conveyed through the conveyor and enter into the feed worm; same will pick-up the vial and place into the star wheel where the vials pick up the caps from the cap-releasing shoe.

The filled and Stoppard vials having capped placed on their heads then pass towards the Sealing heads. Star wheel will place the vial on lifter bowl and same will hold the vial from bottom and from top. Chucks will grip the vial positively and firmly.

Single sealing roller will seal the vial during the planetary motion of vial and exit star wheel will gain pick-off the sealed vial and place on the conveyor for further operation.

The equipment can be operated either in auto mode or in manual mode. The aluminium seal vibratory bowl fitted with electromagnetic coil with pot, increases or decreases the vibration of feeder bowl. It also sense the presence of cap in the cap releasing shoe & interlocked with ON/OFF main motor and detect the tilted bottle and interlocked with the main motor.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared. The manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Vial Sealing Machine is designed to seal the aluminium caps of various sizes on the vials fed on the continuous line.	Should be able to seal the aluminium caps of various sizes on the vials fed on the continuous line properly.	Process Requirement
Working: The feed vials moving on conveyer belt are fed into an infeed star wheel through in feed worm, star wheel bringing the vial below the sealing head in the subsequent indexing part, mean while the vials pick up a cap from the delivery chute of vial cap bowl, where the body and the neck of the vial are positioned below the rotating head, where the sealing head is performing perfect operation of sealing.	Should be able to seal the aluminium caps of various sizes on the vials fed on the continuous line properly.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	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	Voltage : 220 V Phase : 1 Phase Frequency : 50 Hz	GMP 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
Dimension	1650 (L) x 1804 (H) x 1078 (W) (in mm)
No. of Sealing Head	Nos. : 04
Capacity	60 - 90 Vials/minute
Direction of Machine	Left to Right
Main Motor	Make : REMI (VEM) Type : 03 Phase Induction Motor kW : 0.75 Volt : 415 RPM : 1390 AMP : 1.86 Frequency: 50 Hz Sr. No. : 14 K-592
Gear Box	Make : Yash Worm Gear Unit Model : YGVU Size : 250 Ratio : 10:1 Sr. No. : 12089
Indicators	Nos. : 02 (01 Green for Power ON & Red for Clutch) Type : Led Indicators Volt : 240 V, AC Supply
On/Off Main Switch	Make : L & T (SALZER) Quantity : 01 No.
Start/ Stop Switch	Start : Green Stop : Red Inch : Yellow Type : Push Type Button
Limit Switch	Nos. : 04 Make : ESSER (CE)

 PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VIAL SEALING MACHINE	PROTOCOL No.:

Critical Variables	Acceptance Criteria
MCB	Make : L & T Type : C 16 Volt : 240/415 V
Change Parts	Star Wheel, Centre Guide, Feed Worm, Die, Delivery Chute & Bowl
Conveyor	Nos. : 01
Star Wheel	Nos. : 02 (In feed & Exit Out feed)
Capping Section	Nos. : 01
Vibratory Cap Hopper (Bowl)	Nos. : 01
Dimensions of Vibratory Cap Hopper	440 (H) x 330 (W) (in mm)
VFD A.C. Drive	Nos. : 01 Speed : 0 - 100
VFD Vibration Controller	Nos. : 01 Speed : 0 - 100

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction
1.	Die	SS 316 L
2.	Roller	SS 304
3.	Conveyor	SS 304
4.	Star Wheel	Bakelite
5.	Vibratory Bowl	SS 316 L
6.	Vibratory Bowl Chute	SS 316 L

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is 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.	Safety Requirement
Joints	Welding of joints 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	Safety Requirement

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Vial 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, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) Specifications and Requirements as specified in PO and URS.

(2) Operating and service manual for Vial Sealing Machine.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
db	:	Decibel
RH	:	Relative Humidity
HP	:	Horse Power
SS	:	Stainless steel

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			