DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

VACUUM LEAK TESTER

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

 PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM LEAK TESTER	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM LEAK TESTER**	**PROTOCOL No.:**

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION			

2.0 OBJECTIVE:

- To prepare the Design Qualification document for Vacuum Leak Tester on basis of Design Qualification document 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 of Vacuum Leak Tester (Make: …….).
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings 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 Authorization of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production &Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review of Design Qualification the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of Design Qualification 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 Required. ➢ Identification of components for calibration ➢ Brief Process Description ➢ Safety Features and Alarms • Review of Design Qualification Protocol cum Report after Execution.

5.0 PROJECT REQUIRMENT:

- To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.
- The Vacuum Leak Tester &, its associated components are designed in accordance with cGMP principles.

6.0 BRIEF PROCESS DESCRIPTION :

6.1 Purpose:

Vacuum Leak Tester is a equipment to find out leak in the flexible plastic blown Vials / Ampoules after filling & sealing, which is very essential in Pharma products to check individually on mechanical system like LVP/SVP containers, is a time consuming process, hence as a lot it can be checked under Vacuum in vertical position & then upside down to ensure the checking of complete Vials / Ampoules Surface. This process can be carried out in Vacuum Leak Tester with an adjustable cycle.

6.2 Design Consideration:

Vacuum Leak Tester is rugged, versatile and engineered for reliability and enhances Operational Efficiency that confirms to High Standard Engineering Design / Workmanship, so as to comply with all currently applicable Statutory Regulations, prevailing Safety Rules / Code Engineer Standard and Good Manufacturing Practices (GMP). The equipment is designed by the renowned technocrats from the most advanced electronic & mechanical pool of knowledge available in the Modern Age.

This equipment has a Robust Construction. It is compatible to work in any condition. The equipment can be amended as per the requirement of input as it is Tailor made Machine.

Load ampoules upside down in the perforated trays & load it into the chamber after closing with cover. After loading all trays, close the door & tightened with locking arrangement. Press start button given on Touch screen HMI, which will start Vacuum pump & timer for the cycle as Programmed. After completion of preset time, Vacuum will be released & at the same time chamber will start rotating, which will stop after 180° rotation with the help of metal proxy sensor/limit switch. After that second Vacuum cycle start as soon as Vacuum will be achieved, thro' Vacuum switch & second timer will start. Immediately after completion of second cycle, again chamber will start rotating in reverse

direction & stop with the help of metal sensor/limit switch until it reaches to original position. Along with reverse rotation start, Vacuum will be released. For any leakage liquid accumulated in the chamber, can be drain from bottom drain valve provided below the chamber.

Emergency stop is provided for stop machine; in case of any emergency.

6.3 HMI Features (Standard):

Touch screen HMI provided for Programming & Operating. HMI is mounted on the Front Side of the Machine. It is easy to Maintain and it will safeguard the Electrical related Problems. The Panel Board is built from SS 304 Matt finished sheet. One Main's Switch and Emergency Stop button will be also provided on the Main Panel to ON or OFF the

6.4 Testing*:*

The equipment will be tested continuously for 24 hours at our Plant itself before dispatch. All other Mechanical, Electrical & Electronic Components will be checked by the respective field experts before it will be taken for use. All Fabricated and mechanical parts will also thoroughly checked under strict quality control of our well-equipped QC Department. Quality Checking will include Size, Thickness, and Material of Construction & other unavoidable characteristics of the Spare Parts

6.5 Mounting:

In our equipment, the special attention would not be required for Mounting such as underground earthing (or) any pre-provision at the actual Site of Equipment Operation. Vacuum Leak Tester is mounted on a pedestal fitted on Rectangular S.S. pipe frame thro' two nos. side shafts for the rotation on stand. Through one of the mounting shaft, Vacuum line is connected with a Vacuum pump. Our equipment is free from Vibration.

7.0 EQUIPMENT SPECIFICATION:

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Equipment Parameters:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application:	Vacuum Leak Tester is a equipment to find out leak in the flexible plastic blown Vials	Process Requirement
Working:	it can be checked under Vacuum in vertical position & then upside down to ensure the checking of complete Vials / Ampoules Surface. This process can be carried out in Vacuum Leak Tester with an adjustable cycle.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Switch.	Design Requirement

8.2 Utility Requirements/Location Suitability:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Supply	• Voltage: 220-230 V AC • Phases: 1 Phase • Frequency: 50-60 Hz • Power consumption :310 Watts	cGMP Requirement
Room Condition	Should be able to meet the requirement of clean environment.	Process Requirement
Earthing	Earthing Properly Connected.	Process & Safety Requirement
Chilled Water Supply	Chilled Water inlet & Outlet Pipe Properly Connected.	Process & Safety Requirement

8.3 Technical Specifications/Key Design Features:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Manufacturer	Maharshi Udyog	Design Requirement
Machine sr. No.:	G15016	Design Requirement
Overall Dimension (L x W xH)	2000 x 1100 x 1500 mm (Approx)	Design Requirement
Case Dimension (L x W x H)	610 x 610x 610 mm	Design Requirement
Net Weight	650 Kg (Approx)	Design Requirement
Vial/ Ampoules Cassette Size	For 5 ml & 10 ml LVS/ SVP/WFI oval/Round shape Vial/ Ampoules of Height up to 100 mm. Hight. 1) Ø 15 x 82 mm Height. Vials 2) Ø 15 x 100 mm Height. Vials	Design & process Requirement
Capacity of Chamber	Minimum 13500 Nos.Vials	Design & process Requirement
Chamber Size (W x H x D)	700 x 700 x 795 mm deep Chamber of 8	Design & process Requirement
Chamber Door	One Side Fix & other side 8 Thick SS304 operable door with suitable hinge, Gasket & Lock	Design & process Requirement
No of Tray	6 Tray/ Chamber , of 16 SWG Thick SS 304 with Perforation at bottom & Perforated Top sheet.	Design & process Requirement
Tray Size	665 x 100 mm Height x 795 mm Length for Ø 15 x 82 & 100 mm Height Vials Nos : 6 Nos	Design & process Requirement
Driving Unit	Suitable Driving Arrangement with AC. Motor & Gear box Housed in SS Cage duly Matt Finished. Without Starter/ AC Drive.	Design Requirement
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 PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM LEAK TESTER	PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Main Drive Motor	Make : Crompton Model : YGPH Phase : 3Phase 415 V± V AC Ratio : 30 :1 Sr. No : ISI2468	Design Requirement
Main Drive Gear Box	Make : ‘ Yash ‘ of Suitable Size Model : YGPH Size : 3.00 Ratio : 30:1	Design Requirement
Worm & Worm Wheel for Tilting	Ratio : 45 : 1	Design Requirement
Pulley on Motor	V- Groove Pulley, Sec-B, 3’’ Dia.	Process & Safety Requirement
Pulley on Gear Box	V- Groove Pulley, Sec-B, 3’’ Dia.	Process & Safety Requirement
V-Belt	B-30	Process & Safety Requirement
Chain Wheel	On Gear box & main Shaft T-16 x 5/8’’ P (2 Nos)	Process & Safety Requirement
Control Panel	Make : Maharishi	Process & Safety Requirement
PLC	Make : Schneider	Process & Safety Requirement
Touch Screen HMI	Make : Schneider	Process & Safety Requirement
Vacuum Pump	Make: ACMEVAC pump & Eng. Pvt. Ltd Model : ISP 1500 Sr.No. 163690 LPM : 1500 Vacuum : 0.50 Hg	Process & Design Requirement
Metal Proxy sensor	Make : Autonics Model : PR12-4DP-CN Size : 12 mm Qty : 2 Nos	Process & Design Requirement
Vacuum Sensor	Make : Winter Type : 1/3 DAR,420 MA Sr.No. : LE10030R11	Process & Design Requirement

7.3.1 Material of Construction:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Main Body	SS 304
2.	Vacuum Chamber	SS 304
3.	Chamber Door	SS304
4.	Tray	Aluminum
5.	Drive Unit	SS
6.	Drain Valve	SS

8.4 Safety:

S.No.	PARAMETERS	ACCEPTANCE CRITERIA	REFERENCE
1.	Building Joint	Building Joint Free From Building Burr	cGMP& Safety Requirement
2.	Sharp Edge.	No Sharp Edge Present	Safety & cGMP Requirement
3	Electrical wiring and earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided	Safety Requirement
4.	Oil Level	Oil Level Should be up to Mark	Safety & cGMP Requirement
5.	Lubrication	Gear box Should be Lubricated by Lubricant	Safety & cGMP Requirement
6.	Chilled water Supply	Chilled Water Supply Properly Connected	Safety & cGMP Requirement
7.	Door With Gasket	Rubber Gasket Provided at Door for Properly air Tight Closing	

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

8.5 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying The Vacuum Leak Tester	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowledge, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Purchase Order Copy.
- Any other relevant documents.

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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

AC	:	Alternate current
cGMP	:	Current Good Manufacturing Practice
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
GA	:	General Arrangement
Hz	:	Horse Power
IB	:	Injection block
Ltd.	:	Limited
mm	:	Millimeter
MOC	:	Material of Construction
Nos.	:	Number
Pvt.	:	Private
QA	:	Quality Assurance
SS	:	Stainless Steel
V	:	voltage
VLA	:	Vacuum Leak Tester

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			