DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR LEAK TEST APPARATUS

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

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR LEAK TEST APPARATUS	PROTOCOL No.:

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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)			
HEAD (PRODUCTION)			

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 for **Leak Test Apparatus (Make: ……)** to be installed.
- The equipment shall operate 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 Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification activity. • Reviewed of Design Qualification Protocol cum Report after Execution.
Production	• Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.

Engineering	• Review of Design Qualification 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.
	  • Model, Quantity and Backup Records
	  • Identification of components for Calibration
	  • Material of Construction of all components
	  • Brief Equipment Description
	  • Reviewed of Design Qualification Protocol cum Report after Execution.

5.0 PROJECT REQUIREMENTS:

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.

6.0 BRIEF PROCESS DESCRIPTION:

Leak test apparatus is designed to check leakage sealing Bottles/ tubes etc. It is fitted with vacuum pump, digital microprocessor based timer (15-999 sec) and vacuum gauge Range 150-600 mm Hg.

- Test the integrity of bottles/tubes.
- Operation based on vacuum.

7.0 EQUIPMENT SPECIFICATION:

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application:	Leak Test Apparatus should meet the requirement for inspection of bottles /tubes contain any water seepage.	Process Requirement
Working:	Leak Test Apparatus should be capable of maintaining vacuum in jar to facilitate water seepage through any leakage to detect sealing quality of bottles/tubes	Process Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Electrical Supply:	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in service area.	GMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Technical			
1.	**Equipment**	Leak Test Apparatus	Design Requirements
2.	**Sr. No.**	19090604	Design Requirements
3.	**Make**	ESICO INTERNATIONAL	Design Requirements
4.	**Model**	1961	Design Requirements
5.	**Dimension**	366 x 310 x 230mm	Design Requirements
6.	**Weight**	12 Kg	Design Requirements
7.	**Dessicators size**	12 Inch	Design Requirements
8.	**Display**	20 X4 line	Design Requirements
9.	**Dessicator**	Polycarbonate	Design Requirements
10.	**Vacuum level**	150-600 mm Hg	Design Requirements
11.	**Vacuum setting**	Less than 400 mm Hg ± 10 mm Hg	Design Requirements
12.	**Keyboard**	16 soft touch key	Design Requirements
13.	**Hold time**	15-999 sec	Design Requirements
14.	**Setup data**	Facility for 6 different test setup available	Design Requirements
15.	**Printer**	Provision for the attachment of dot – matrix printer with centronics parallel port interface available	Design Requirements
DIGITAL PRESSURE GAUGE			
16.	**Make**	Keller	Design Requirements
17.	**Range**	-1 to 30 bar	Design Requirements
18.	**Model**	Leo 2	Design Requirements
19.	**Serial no.**	59722	Design Requirements
20.	**Resolution**	0.001	Design Requirements
VACCUM GAUGE			
21.	**Make**	VIGA	Design Requirements
22.	**Range**	-760 to 0 mmHg	Design Requirements
DIGITAL MULTIMETER			
23.	**Make**	MASTECH	Design Requirements
24.	**Model**	NS	Design Requirements

S.No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
25.	**Serial no.**	NS	Design Requirements
26.	**Resolution**	20mmHG	Design Requirements
DIGITAL STOP WATCH			
27.	**Make**	Racer	Design Requirements
28.	**Model**	306	Design Requirements
Electrical			
29.	**Voltage rating**	230 V ± 10% , 50 Hz . AC	Process Requirements
30.	**Power Supply**	AC Mains , 230 Volts, 500 Watt	Process Requirements
31.	**Vacuum Pump**	For Vacuum	Process Requirements
32.	**Vacuum Gauge**	150-600 mm Hg	Process Requirements
33.	**Digital timer**	15- 999 sec	Process Requirements

8.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Reference
1.	**Body**	Polycarbonate	Process Requirement

8.5 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

8.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Leak Test Apparatus	Selection of Vendor is done on the basis of review of vendor. Criteria for review were 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) The equipment shall confirm to the specifications and requirement.

(2) Operating and service manual for Leak Test Apparatus.

Checked By
Engineering
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date:……

9.0 DOCUMENTS TO BE ATTACHED:

- Approved Design and Specifications.
- 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:

cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
db	:	Decibel
DQ	:	Design Qualification
GA	:	General Arrangement
LTA	:	Leak Test Apparatus
Ltd	:	Limited
MCB	:	Miniature Circuit Breaker
MOC	:	Material of Construction
RH	:	Relative Humidity
URS	:	User Requirement Specification

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			