DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR LEAK TEST APPARATUS

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

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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)			

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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**.
- 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	• Initiation, Review and Approval of the Qualification Protocol cum Report • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review 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 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. ➢ Material of construction of Product Contact Parts. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Review of Qualification Protocol cum Report after Execution.

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5.0 BRIEF PROCESS DESCRIPTION:

Leak test apparatus is designed to check leakage in the blister packs, strip, vacuum sealing bags etc. is used to test for the integrity of packed strips, blisters and small sachets containing tablets, granulates liquids and so on. The instrument is used to test the quality of the packaging process and to check that the seals enclosing the product are perfectly intact. It is fitted with vacuum pump, digital microprocessor based timer (up to 999 sec) and vacuum gauge 20" of Hg.

- Test the integrity of strips, blisters and bottles.
- Operation based on vacuum.

6.0 EQUIPMENT SPECIFICATION:

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

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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The leak test apparatus should be able to inspect whether the vial sealing contains any leakage or if the vial is broken or not properly sealed.	Leak Test Apparatus should meet the requirement for inspection of vial contains any water seepage.	Process Requirement
Working: Working of Leak Test Apparatus.	Leak Test Apparatus should be capable of maintaining vacuum in jar to facilitate water seepage through any leakage to detect sealing quality of vials	Process Requirement

7.2 UTILITY 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 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

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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Critical Variables	Acceptance Criteria
1.	**Equipment**	Leak Test Apparatus
2.	**Model**	LTA-300
3.	**Dimension**	41 cm x 61 cm x 22 cm
4.	**Conveyer Height**	As per Line Height
5.	**Weight**	15 Kg
6.	**Power supply**	AC mains, Voltage : 230 volts 500 watts
7.	**Vacuum pump**	For vacuum
8.	**Vacuum gauge**	For measuring pressure level 20” Hg Accuracy : ± 0.5% of full scale Least count : 0.2 In/ Hg Mounting type : panel mounting 1/8” B.S.P Threading
9.	**Digital timer**	Upto 999 sec

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Reference
1.	**Body**	SS -304 Q Fabrication	Process Requirement

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 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.

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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
cGEP	:	Current Good Engineering Practice
PO	:	Purchase Order
DQ	:	Design Qualification
MOC	:	Material of Construction
GA	:	General Arrangement
MCB	:	Miniature Circuit Breaker
db	:	Decibel
RH	:	Relative Humidity
AMP	:	Ampere

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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			