



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION (URS) FOR LEAK TEST APPARATUS

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FOR
LEAK TEST APPARATUS



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Signing of this approval page of URS indicates agreement in this document. Should Modifications to the user Requirements Specification approach become necessary, an addendum will be prepared and approved.

Prepared by	Signature	Date
Officer-Quality Control		
Officer-Quality Assurance		
Executive – Quality Assurance		
Checked By	Signature	Date
Manager- Quality Control		
Manager – Quality Assurance		
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Head Quality		
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1.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for the Leak test apparatus

The URS shall be recognized as the integral part of the procurement agreement with the selected equipment vendor. The equipment supplier or vendor shall abide by the information and condition set forth by this document as well as purchasing and delivery terms and conditions.

The leak test apparatus shall be located at wet lab of Quality control area.

Checking the leak test is a very essential step during tablets packing. The leak test is an ideal instrument to check blister packs, strips for leak test.

The utilities and space involved needs to be discussed prior to the purchase of the equipment.

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2.0 OVERVIEW DEFINITION:

The Leak test apparatus tester shall have the following features:

- 2.1 The instrument is equipped with long lasting vacuum pump, which gives higher level of vacuum in shortest possible time. Die pressed polycarbonate vacuum desecrator sustains vacuum for a long time.
- 2.2 A vacuum gauge is provided to indicate vacuum level, which is connected to isolation valve to disconnect the vacuum source.
- 2.3 Its amazing compactness saves lot of valuable place in process laboratories.
- 2.4 A 0 to 5 minute timer helps operator to do the other work.

c) The Leak test apparatus shall be used primarily for :

Leak testing of Blister and Strip



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d) **Technical Specifications:** Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Desecrator Diameter	300 mm
Desecrator	Polycarbonate
Vacuum Level	550 mm of Hg
Rating	230 VAC \pm 10 V, 5A, 50 Hz, Single phase
Timer	5 Minute (Mechanical)

e) **Cleaning Requirements:** Manual cleaning with Lint free wipe.

f) **The machine is to be used at the following environmental conditions:**

Indoor Temperature: NMT 24°C

Relative Humidity: NMT 55%

g) **Base Utilities Available:**

Electrical: Single Phase, 230V \pm 10% 50 Hz

h) **Control system requirements:** Manual.

3.0 OPERATIONAL REQUIREMENTS:

3.1 OPERATION:

The system shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental standpoint.

3.2 POWER FAILURE/RECOVERY:

The system will stop automatically upon loss of electricity, and will require operator intervention to re-start.



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4.0 SALIENT FEATURES:

4.1 COMPATIBILITY AND SUPPORT:

4.1.1 Utilities

The Supplier shall specify utility data. The User shall ensure that the utilities are available at the time installation.

4.2 MATERIAL OF CONSTRUCTION:

NA

4.3 INSTRUMENTS AND CONTROLS:

Control Panel: The control panel should be provided with main switch on/off push buttons with indication lamps.

5. MAINTENANCE:

System shall be maintained on a schedule as indicated by the supplier. Supplier is to provide (at minimum) the following maintenance instructions:

- All sub-systems provided (Maintenance and operation manuals of vendor equipment)
- A comprehensive lubrication list and recommended lubrication schedule
- A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)
- Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manual.

6. DELIVERY:

The Disintegration test apparatus with all options, equipment, and the documentation listed below, shall be delivered.

Delivered should be confirmation of the purchase order.

8. DOCUMENTATION:

The Supplier shall provide the documentation for preliminary review. The Supplier shall provide documentation reflecting “as-built” condition with final delivery.

All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect “As-Built” condition.



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All documents shall be in English language and supplied with hard copies and supplied in the format identified for each document:

- Installation Qualification
- Operational Qualification
- Operator, Maintenance and Service Manuals
- Process and Instrumentation Diagram (P&ID)
- Instrument Listing
- Machine Assembly Drawings
- Bill of Materials
- Spare Parts List along with quotation
- PLC Program Printout
- Test certificates
- Material of construction