USER REQUIREMENTS SPECIFICATIONS

FOR

TABLET HARDNESS TESTER

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR TABLET HARDNESS TESTER

Prepared by	Signature	Date
Quality Control		
Production		
Quality Assurance		
Checked By	**Signature**	**Date**
Quality Control		
Quality Assurance		
Approved By	**Signature**	**Date**
Head Quality		
Projects		
Plant Head		

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR TABLET HARDNESS TESTER

TABLE OF CONTENTS

1.0 Introduction

2.0 Overview Definition

3.0 Operational Requirements

3.1 Operation

3.2 Power failure / Recovery

3.3 Safety features

4.0 Salient Features

4.1 Compatibility and support

4.2 Material of construction

4.3 Instruments & controls

5.0 Maintenance

6.0 Delivery

7.0 Documentation

USER REQUIREMENT SPECIFICATION FOR TABLET HARDNESS TESTER

1.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for the Tablet Hardness tester.

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 tablet Hardness tester shall be located at instruments lab in Quality Control area. Hardness is one of the most important aspect while compression of Tablets, it gives brief idea about the tablet's resistance to crushing. Hardness also has a significant impact on the dissolution rate of the Tablet. Hence determination of the tablet hardness is one of the most important parameters while compression.

The Tablet Hardness tester shall be interfaced with following components.

1. Tablet Hardness Tester – main Unit (Dr. Schleuniger Pharmatron AG).
2. Load Cell Compartment (attached to the main Unit)
3. Keyboard
4. 5 kg Cast Cupper weight with certificate
5. Power supply cord
6. 10.0 mm mechanical tablet of SS
7. Plastic collection tray
8. Hand held brush

The utilities and space involved needs to be discussed prior to the purchase of the equipment. The unit shall be feasible to be installed in the current building facility.

USER REQUIREMENT SPECIFICATION FOR TABLET HARDNESS TESTER

2.0 OVERVIEW DEFINITION:

The tablet tester shall have the following features:

2.1 Tablet Hardness Tester Dr. Schleuniger Pharmatron - 8M will allow to measure tablet Hardness in Newtons, Kilopounds, Strong cobbs or user defined unit of measure.

2.2 It can also measure tablet diameter and thickness in either mm or inches.

2.3 It also has a function of measuring weight in either g or mg. Up to 100 measurements of each parameter can be taken and / or stored for statistical analysis.

2.4 This hardness tester calculates the mean, maximum, minimum, range, absolute standard deviation and relative standard deviation of data.

2.5 Statistical data may be printed in graphical form using one of the graph options. It can define both tolerance (T1 and T2) ranges and valid range for measurement, which eliminates unacceptable values from the statistics.

2.6 Tablet Hardness Tester Dr. Schleuniger Pharmatron - 8M has ten input / output ports for external communications.

2..7 The host / terminal port allows the tester to be attached to any serial terminal, allowing information to be passed between the tester and the host computer. This could be used to enter configuration information as well as collect data for external analysis.

2..8 The centronics printer port allows the user to connect the tester to any compatible parallel printer.

2..9 The RS232C port 1 connection allows the user to connect the tester to any compatible serial printer.

2..10 The RS232C port 2 allows the user to connect the tester to additional test equipment.

2..11 The CAN in port is used for networking local CAN compatible devices.

2..12 The CAN out port is used for networking local CAN compatible devices.

2..13 The thickness port is the data port through which data from the external thickness gauge is transferred to the tester.

2..14 The balance port is the data port through which data from the balance is transferred to the tester.

2..15 The optional keyboard port allows the entry of product information, limits and configuration information from a keyboard.

2..16 The external start port is for a removes switch that can be used for functional equivalent to the Run button on the front plate.

2.17 The tester has powerful micro-processor based control board. The Micro-Processor controls the operations of the machines, and computes the statistics for the tablet measurements.

2.18 The hardness reading are taken via a load cell, and converted into the appropriate units. Available unit scales are Newtons, Kilopounds, Strong cobbs or the User Defined unit of measure.

2.19 Diameter and the Thickness (internal) data readings are taken by using the load cell in conjunction with a stepper motor. Both sets of units are programmed via the 8M software.

2.20 Operators can enter the Product Name. Number, Batch ID, Press ID, Container Number, Operator and Comments with a keyboard, Up to 100 samples of weight, Thickness, diameter and hardness can be collected, reported and stored (excluding Product 0) in a single test sequence. The data can not, however, be stored for batch (multiple test) evaluation purposes .

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

Hardness testing of tablet

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

ITEM	SPECIFICATIONS
Physical Dimensions	420 x 150 x 185 mm
Weight	10 Kg
Environmental requirements	32° to 100° F 0° to 38° C Up to 90% RH
Power Supply	115 / 230 V, 50/60 cycles, auto switch
Hardness Capacity and Tolerance	50 Newtons ± 1% of full scale 400 Newtons ± 1% of full scale 500 Newtons ± 1% of full scale 800 Newtons ± 1% of full scale 1000 Newtons ± 1% of full scale
Sample Diameter	33 mm. (max)
Cycle Time	25 Tablets / 3 minutes (typical)
Measuring Unit	Hardness
	N (Newton's)
	Kp (Kilopond, 1 Kp = 9.81N)
	Sc (Strocobb, 1 Kp = 1.43 Sc)
	Diameter
	mm or Inch
Voltage	220V / 50-60 Hz or 110V / 50-60 Hz
Test Method	Manual or Automated

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 ± 10% 50 Hz

h) **Control system requirements:** Manual / Semi automatic.

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:

In the event of power failure. The system will stop automatically upon loss of electricity and will require operator intervention to re-start.

3.3 SAFETY FEATURE:

The apparatus should have power failure detection facility. If the power fails during the test, the remaining test is completed when the power supply is resumed.

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 and that the utility supply lines and piping are terminated with fittings or connections.

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.

7. 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.

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
- Performance qualification
- Operator, Maintenance and Service Manuals
- Process and Instrumentation Diagram (P & ID)
- Instrument Listing
- Machine Assembly Drawings
- Bill of Materials
- Test certificates
- Material of construction

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR TABLET HARDNESS TESTER