



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR MOISTURE ANALYZER

USER REQUIREMENT SPECIFICATIONS
FOR
MOISTURE ANALYZER



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR MOISTURE ANALYZER

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 Assurance		
Officer-Production		
Officer-Engineering		
Checked By	Signature	Date
Manager- Production		
Manager - Engineering		
Approved By	Signature	Date
Head Quality		
General Manager – Projects		
Plant head		



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR MOISTURE ANALYZER

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 FAT**
- 7.0 Delivery**
- 8.0 Documentation**



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR MOISTURE ANALYZER

1.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for the Moisture Analyzer.

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 Moisture Analyzer shall be located at IPQC room of manufacturing area.

The Moisture Analyzer should have motorized heating unit which is semi automatic and fully automatic determination of drying parameters with **ASAP** features.

The Moisture Analyzer shall be interfaced with following components.

1. Moisture Analyzer with Data Printer printing facility.
2. Kit of Standard Accessories :- Power cord, Pan Support, Shield disk, Dust cover to keypad, 80 disposable aluminum sample pan, 1 pair of forceps, 3 cards with brief instruction in six different languages
3. Temperature adjustment Set

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.

2.0 OVERVIEW DEFINITION:

The Moisture Analyzer shall have the following features:

- 2.1 Moisture analyzer should be Infrared Moisture measuring instrument type, a compact design with ceramic IR heating element (MA 50 C) or Halogen heating element (MA 50 H).
- 2.2 The data interface port is a menu-driven software for operator guidance, keypad with 10 numeric keys, 50 g weighing capacity.
- 2.3 In conjugation with the YDP01 MA data printer it can generate the printouts in compliance



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR MOISTURE ANALYZER

with quality management / assurance guidelines.

c) **The Moisture Analyzer apparatus shall be used primarily for:**

Moisture analysis of Tablet granules.

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

ITEM	SPECIFICATIONS
Dryer functions:	
Heating element	Ceramic IR heater or round Halogen lamp
Temperature range	30 – 230°C / 86 – 392°F
Temperature increments	Adjustable in 1°C increments
Temperature adjustment	With YTM03MA temperature adjustment set
Weighing Function:	
Weighing capacity	50 g
Readability	1 mg, 0.01% Moisture Content
Repeatability	Sample weight = 1g : 0.2% Sample weight = 5g : 0.05%
External calibration weight (of at least accuracy)	50 g (F1)
Sample Pan Dimensions	Ø 90 mm
Drying Parameters:	
Drying Programs	Standard, Quick
Drying Time	6 sec. To 999 min
Number of programs	5
Shutoff criteria	Fully automatic, semi automatic, asap, time (1 x 999 min), manual
Display for analysis results	Moisture, dry weight, RATIO, weight loss, residual weight (g or g/kg)
Analyzing Hardware	
Dimensions (L x W x H)	350 x 453 x 156 mm



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR MOISTURE ANALYZER

Net Weight (approx.)	6.5 kg
Voltage	230V or 115 V selectable by replacing the heating unit, -15%/ +10%
Frequency	48 – 60 Hz
Fuses	2 (neutral conductor / phase), 6.3 AT, 5 x 20mm
Operating temperature range	10 – 30°C (50 – 86°F)
Power consumption	700 VA max.
Built-in interface	RS 232C
Format	7or 8 bit ASCII, 1 start bit, 1 or 2 stop bit
Parity	Space, odd or even
Transmission rates	150 to 19200 baud
Handshake	Software or Hardware
Digital Input	1, adjustable function
Digital output	4, operating state of analysis

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.

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.



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR MOISTURE ANALYZER

3.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall protect product against damage. The system will stop automatically upon loss of electricity, air, or other major utility 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. FAT:

The manufacture should allow factory acceptance test (FAT) to be performed on completion of the manufactures of the machine .The observation indicated during FAT should be



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR MOISTURE ANALYZER

complied in agreement before shipment of the machine

7. 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.

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
- Control Schematics
- Control Panel Assembly Drawings
- Machine Assembly Drawings
- Bill of Materials
- Spare Parts List along with quotation
- PLC Program Printout
- Test certificates
- Material of construction