User Requirement Specification:

USP 81 Antibiotic Zone Reader

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1. Introduction

1.1 Objective

The objective of this URS is to define and document the requirements of the User Requirement Specification for USP 81 Antibiotic Zone Reader at microbiology laboratory located in Sina Darou Pharmaceutical site.

TRINITY V3 USP 81 Antibiotic Zone Reader color digital imaging technology automates zone reading and calculations for the USP (United States Pharmacopeia) 81 cylinder-plate assay. This greatly improves the accuracy, speed and standardization of reading.

The Supplier of the system is required to adhere to the content of this document; any deviations proposed must be clearly identified and justified by the Supplier.

1.2 Scope

This specification is intended to provide a list of the machine characteristics: some details or additional features may be omitted, but no characteristic, which is not mentioned, can affect the machine's compliance to the requirements declared in this document.

The scope of this URS is limited to the User Requirement Specification at Sina Darou company

The URS details the following requirement types:

- System description
- compliance requirements
- process and operational requirements
- Safety & Interlocking

2. System description

Ref.	System description
	2.1 System description
U1.	The system shall be installed in microbiology laboratory at Sina Darou pharmaceutical site.

3. Requirements

Ref.	Requirements

3.1 compliance requirements	
U2.	The equipment shall technically suitable for the specific task and for clean, efficient, safe and secure operation and maintenance and shall have its systems tested and verified as being in correct order to enable full process validation to be performed.
3.2 process and operational requirements	
3.2.1 Capacity	
U3.	One 10 mm diameter petri dish containing 6 cylinders per each petri dish.
3.2.2 General	
U4.	Supplier should supply the documentation, and the machine test qualifications, including: • Installation drawing, • P&ID, • Electrical wiring diagram, • As Built drawing, • Operating Manual, • Maintenance Instructions, • Safety Instructions, • Comprehensive recommended spares parts list, • FAT Protocol, • SAT Protocol, • Design qualification, • Installation qualification documents, • Operational qualification documents.
U5.	• Factory Acceptance Test (FAT) is performed at the supplier site prior to shipping, • Site Acceptance Test (SAT) is performed at the manufacturer site to be witnessed by manufacturer staff, • The supplier has to specify and document the outline and program of the instruction training for the operating and technical personnel.
3.3 Technical Data	
3.3.1 Dimensions:	
U6.	Width: 34 cm (13.5 in) - Shipping Width: 58 cm (23 in) Height: 47 cm (13 in) - Shipping Height: 46 cm (18 in) Depth: 33 cm (18 in) - Shipping Depth: 44 cm (17.5 in)
3.3.2 Voltage:	
U7.	100 – 240 Volts 50 – 60 Hz
3.3.3 Loading System for Test Plates:	
U8.	Drawer fits test plates up to 150mm round Adapter rings available for unique test plate sizes
3.3.4 Image Capture:	
U9.	Full color digital camera

	High Resolution 1280 x 1024 pixels Unlimited number of test plate images may be saved and printed
3.3.5 Image Precision:	
U10.	0.10 mm for colony size detection and zone diameter reading 0.15 mm for colony size discrimination
3.3.6 Lighting:	
U11.	Non-breakable LED light source Lifespan 100,000+ hours Over sample lighting Under sample lighting Darkfield illumination
3.3.7 Cabinet Design:	
U12.	Closed cabinet No ambient light interference
3.3.8 Monitor:	
U13.	15 inch Touch Screen Mounted to reader cabinet CE, UL, and FCC certified
3.3.9 Calibration:	
U14.	Zone diameter measurement Calibration required after software installation and if system is physically moved
3.3.10 Environmental Requirements:	
U15.	Temperature: 10-45°C Humidity: 0-90% Similar to requirements for personal computer operation
3.3.11 Maintenance:	
U16.	No routine maintenance required Contains no motors, no scanners, no mirrors, no moving parts, no breakable light source
3.3.12 Software Compatibility:	
U17.	TRINITYTM V3 and BIOMIC® V3 software modules
3.3.13 Bar Code Reader	
U18.	optional
3.3.14 Electronic Caliper:	
U19.	Linked to the computer by USB cable Measuring range: 0-150mm Resolution: 0.01mm Precision: 0.02mm Repeatability:0.01mm Measurement unit: millimeter
3.3.15 Test Plate Adapter:	
U20.	90 mm Test Plate Adapter Ring

3.3.16 Power Supply with Cord:	
U21.	12 Volt Power supply UL and CE certified
3.3.17USB 2.0 Cable	
3.3.18 Product Manual	
3.3.19 Software CD	
3.3.20 Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) validation Protocol documents	
3.3.21 Test Plates Read:	
U22.	90-100 mm round
3.3.22 Reading Time:	
U23.	Less than 1 second per test plate
3.3.23 US FDA, United States of America Food and Drug Administration:	
U24.	510(k) Reviewed - K944319 and K932122
3.3.24 Methods:	
U25.	US Methods - USP (United States Pharmacopoeia), US-FDA, CFR (Code of Federal Registry), AOAC (Association of Analytical Communities) EP (European Pharmacopoeia) BP (British Pharmacopoeia) JP (Japanese Pharmacopoeia) Meets GLP (Good Laboratory Practices) requirements
3.3.25 Zone Measurement Accuracy:	
U26.	Displays 1 or 2 decimal places 0.10mm precision for measurements Threshold and sensitivity settings for difficult plates
3.3.26 Log Options:	
U27.	Natural Log Base 10 Log
3.3.27 Calculation Features:	
U28.	Instant concentration and potency calculation upon completion of reading all plates Plate to plate variation automatically accounted for in calculations Display us to 5 decimal places on calculated values
3.3.28 US Method Features:	
U29.	Option to check zone measurements for outliers Option to plot concentration on y-axis or x-axis Option to use corrected reference to calculate unknowns Option to display standard curve before reading unknowns

	Option to calculate concentration as a percentage of reference Displays raw data and graph on-screen to review, save and print Plots standard curve with unknown and known concentrations, and outlying points clearly displayed Calculates correlation coefficient, standard deviation, sample concentrations and original concentration values
3.3.29 Electronic Records:	
U30.	Meets 21 CFR Part 11 (Code of Federal Registry) for electronic signature requirements Three level access control with user ID and password (Read Only, Standard User, Administrator) Password expiration settings Minimum password and user ID length settings Secure, encrypted database User access log and data audit trails All changes to users, configuration, and system settings are logged All test results are marked with user ID, date, and time
3.3.30 Data Export:	
U31.	Test results including raw measurements may be exported in text or binary format to be read by other software programs
3.3.31 Recording Device:	
U32.	Electronic caliper records zone diameters via USB port directly into software
3.3.33 Plate Sizes:	
U33.	All plate sizes including 243mm bioassay dishes (NUNC in Denmark)
3.3.34 Calculation Features:	
U34.	Correlation coefficient Standard deviation Sample concentrations Original concentration values Results from two identical test plates can be averaged
3.3.35 Display Features:	
U35.	Raw data Standard curve graph including unknown and known concentrations, and outlying points
3.3.36 COMPUTER REQUIREMENTS	
U36.	• Processor: Pentium 4 or equivalent (minimum), Core 2 Duo (recommended for optimal performance) • RAM: 512 meg (minimum) 2 gig (recommended) • Operating System:

	Windows XP, Windows Vista, or Windows 7 • USB 2.0 ports: 3 available (minimum) • Internet Connection: Strongly recommended • Surge Protector
3.4 Standards	
U37.	• Manufacturing Quality and Product safety are audited by internal company procedures consistent with: ✓ ISO 13485: 2003 ✓ US-FDA Good Manufacturing Practices ✓ GMP/QSR Regulations • Council Directive 98/97 EC for “in vitro” diagnostic medical devices: ✓ Conforms
3.4 Supplier	
U38.	The Recommended suppliers are as follows: ✓ TRINITY V3 USP 81 Antibiotic Zone Reader from Giles Scientific Inc