



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Colony Counter

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 6

Name of Equipment: Colony Counter

Document Reference Number:

Effective Date:



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Colony Counter	Protocol No.:
Functional Area: Quality Control	Page No.: 2 of 6

1.0 Approval:

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
Checked By	Signature	Date
Reviewed By	Signature	Date
Approved By	Signature	Date



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Colony Counter

Protocol No.:.....

Functional Area: Quality Control

Page No.: 3 of 6

Table of Contents		Page No.
1.0	Approval	2
2.0	Table of Content	3
3.0	Introduction	4
4.0	Overview Definition	4
5.0	Operational Requirements.	5
5.1	Operation	5
5.2	Power failure / Recovery	5
5.3	Emergency stop	5
5.4	Alarms and Warnings	6
6.0	Salient Features.	6
6.1	Compatibility and support	6
6.2	Material of construction	6
6.3	Instruments & controls	6
7.0	Maintenance	7
8.0	Delivery.	7
9.0	Documentation	7



USER REQUIREMENT SPECIFICATION

Name of Item: Colony Counter

Protocol No.:.....

Functional Area: Quality Control

Page No.: 4 of 6

3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for a Microbiological Colony counter. The URS is provided to aid the user through the important components, variables and options necessary to procure a functional Microbiological Colony counter that meets the User Requirement in the most cost effective method.

The URS is provided to the supplier to provide a price quote for the Microbiological Colony counter, including design and manufacture of the equipment.

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

The Colony counter shall be installed in Biotesting Lab of Microbiology section of QC Department.

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

4.0 OVERVIEW DEFINITION:

4.1 The Colony Counter shall have the following features:

- 4.1.1. The Colony Counter shall LCD display screen to show the count.
- 4.1.2. The Colony Counter shall be designed to sense the pressing of marker pen tip and showing on screen by increasing it by one.
- 4.1.3. The Colony Counter shall be provided a film base to the Petri plate, which will illuminate by a white light to study plate properly.
- 4.1.4. The Colony Counter shall have provided with pen for colony counting.
- 4.1.5. The Colony Counter shall provide with a beep sound to each press of marker pen.

4.2 The colony counter shall be used for:

For the counting of the Number of colony.

4.3 Technical Specifications:

- 4.4.1 Counting range** : 0 to 9999 colonies.
- 4.4.2 Magnifying lens** : Not less than 10X
- 4.4.3 Marker pen** : With permanent marker pan



USER REQUIREMENT SPECIFICATION

Name of Item: Colony Counter	Protocol No.:
Functional Area: Quality Control	Page No.: 5 of 6

4.4 The machine is to be used at the following environmental conditions:

4.4.1 Temperature : NMT 24 °C

4.4.2 Relative Humidity: NMT 55%

4.5 Base Utilities Available:

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

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The instruments operation shall be safe, smooth both from user and environmental standpoint.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall shut off automatically. And acquire operator involvement to start.

5.3 SAFETY FEATURE:

The system shall be stop safely in emergency.

5.4 ALARMS AND WARNINGS:

The Colony Counter should not any such facility.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT:

ELECTRIC CONTROL:

The Supplier shall utilize controller that shall include a communication port.

UTILITIES:

The Supplier shall specify utility requirements. The User shall ensure that the utilities are available and that the utility supply lines and piping are terminated with fittings or connections.



USER REQUIREMENT SPECIFICATION

Name of Item: Colony Counter

Protocol No.:.....

Functional Area: Quality Control

Page No.: 6 of 6

6.2 MATERIAL OF CONSTRUCTION:

Metal and Glass

7.0 MAINTENANCE:

Do's and Don'ts to be provided

- 7.1 Preventive maintenance system and checks to be provided (Maintenance and operation manuals of vendor equipment).
- 7.2 A comprehensive lubrication list and recommended lubrication schedule.
- 7.3 A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list).
- 7.4 Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manuals, DQ, Electrical drawing.

8.0 DELIVERY:

The Colony counter with all options, equipment, and the documentation listed below, shall be delivered to Client Site. Delivery should be confirmation of the purchase order.

9.0 DOCUMENTATION:

- 9.1 The Supplier shall provide the documentation for preliminary review. The Supplier shall provide documentation reflecting "as-built" condition with final delivery.
- 9.2 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.
- 9.3 All documents shall be in English language and supplied with hard copies and supplied in the format identified for each document:
- 9.4 Design qualification
- 9.5 Installation Qualification
- 9.6 Operational Qualification
- 9.7 Maintenance and service manuals
- 9.8 Instrument listing
- 9.9 Material of construction