USER REQUIREMENT SPECIFICATION (URS)

FOR

LIQUID PARTICLE COUNTER (LPC)

Department : Quality Control

URS No. : ……..

Supersede : Nil

USER REQUIREMENT SPECIFICATION

Name of Item: Liquid Particle Counter	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 2 of 7

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Issued to mfg / supplier by purchase department _____

1.0 Approval:

Activity detail	Name of person	Designation	Signature	Date
Prepared By				
Reviewed By				
Approved By				

2.0 Change History:

Revision number	Revision details	Date of revision

3.0 Purpose:

The purpose of the user requirement for Liquid Particle Counter is:
To define the requirement for selection of Liquid particle counter for intended use
To provide a specification to the vendors for their submission of quotation.
To ease the selection process of vendors.

4.0 Scope:

4.1 This document is applicable for Liquid Particle Counter intended to use at manufacturing plant.

4.2 The specification and criteria given in this document is to be considered but should not be limited to this.

5.0 Specifications:

5.1 Description of Equipment/System:

The Liquid particle counter shall have following components.

- Counter
- Sensors
- Data collection system
- Measurement devise
- Software

The detail description of the components is as follows;

5.1.1 Counter

- Data transfer port
- Power supply port

5.1.2 Sensors

- Laser diode or light obscuration type

5.1.3 Data collection system

- A data collection unit like Computer, CD or multimedia card shall be present with equipment

5.1.4 Measurement device

- Liquid particle counter shall contain a suitable measurement devise to measure particles from 1-200 µm. Liquid particle counters built with higher measurement range are preferable.

5.1.5 Software

- LPC must have a software for overall command on system.

5.2 Identification number and location:

Equipment Name	Identification Number	Location
Liquid particle counter	……..	Micro Laboratory

5.3 Intended use:

Operation of equipment depends upon the production output; the equipment should be designed to work continuously for 3 shifts per day.

5.4 Intended type of material to be handled:

This will include handling of drug products;

- Solid & Liquid pharmaceutical raw materials
- Ophthalmic dosage forms
- Liquid injectables
- Water for injection

5.5 Construction:

Not Applicable

5.6 Capacity:

The Liquid particle counter must be capable for routine laboratory analyses.

5.7 Electrical construction:

Not applicable

5.8 Control parameters:

Liquid particle counter can be used according to USP, BP and EP procedure. LPC shall analyze low injection volume and shall be built with exchangeable syringes. Facility of flushing shall be present in LPC. Alarm levels for pass/fail criteria shall be created by LPC. Various flow rates can be selected by LPC. The apparatus should be calibrated using suitable certified reference materials consisting of dispersions of spherical particles of known sizes between 10 µm and 25 µm.

5.9 Acceptable tolerance for control parameters:

Analysis volume	:	100 µl to -100 ml
Syringes	:	1, 5, 10, 25 ml
Flow rate	:	5-50 ml/minute
Operation mode	:	Measurement, flush, performance test (USP, IP and EP) and calibration
Working Environment	:	+15-30^{0}C, 20-80% RH non condensing

5.10 Type of control System:

Software must supply as standard and allows controlling, monitoring and managing everything from LCD keyboard or computer.

Instrument gets the security functions like password protection and audit trail.

5.11 Feasible parameters to be set:

Name of user, Name of product, Batch No. / A.R. No., sample size, sample volume, flow rates, sample limits and storage options and related pharmacopeias.

5.12 Parameters to be indicated by control systems:

- Time and date.
- Formatting Format for recording data with company's name in header.
- Analysis details.

5.13 Available utilities:

- PC and Printer shall be provided
- Utilities required for electric connection shall be provided.
- Space and bench for LPC shall be provided.
- Laminar Air Flow unit for controlled environment shall be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

Software employed for having a control on Liquid particle counter, must be complying with following 21 CFR part 11 regulation of USFDA;

- Secure database of results and methods
- Password/User ID controlled user login system
- Password/User ID controlled data authentication and review
- User In-Activity automatic log off
- Digital Signature
- System changes checked with user ID and password.
- Calibration standard shall be provided

5.16 Delivery Address:

……..

6.0 Safety:

Proper equipment earthing..

7.0 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing will be provided that includes:

- Consumable wear parts
- Parts which are easily broken
- Parts, which can wear out, and are long lead time availability.
- Electronic components those are not readily available from a local source to the user.

- The Supplier will either stock frequently required spare parts, or provide the manufacturer name and part number for those parts.

7.2 Support:

- Start-up Support
  Start-up support shall consist of full time assistance on the User's site for installation, start-up and commissioning.
- Training
  User training shall consist of equipment training by a qualified trainer.
  Certificates of training shall be provided for each person completing the training program.
- Post Start-up Support
  Post start-up support shall consist of user site visits for a period of 1 year after the completion of commissioning activities as and when required.
- Technical Support
  Technical support shall be available as and when required.

8.0 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or PDF
2.	Software guide	Paper or PDF
3.	Qualification documents	Paper
4.	Spare parts list	Paper
5.	List of users	Paper

9.0 References:

United States pharmacopoeia, British pharmacopoeia, In house