USER REQUIREMENT SPECIFICATION (URS)

FOR

VISCOMETER

Department : Quality Control

URS no. : …….

Supersede : Nil

USER REQUIREMENT SPECIFICATION

Name of Item: Viscometer	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 2 of 6

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Issued to mfg / supplier by purchase department _____

USER REQUIREMENT SPECIFICATION

Name of Item: Viscometer	**Protocol No.:**.....
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1.0 Approval:

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

2. Change History:

Revision number	Revision details	Date of revision

3.0 Purpose:

The purpose of the user requirement for Viscometer is:
To define the requirement for selection of Viscometer 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 Viscometer 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 Viscometer shall have following components.

- Spindles
- Software
- Spindle rack
- Temperature probe
- Lab stand
- Carrying case
- Viscosity standards

The detail description of the components is as follows;

5.1.1 Software

- Allow for the creation of customized test programme used in data collection.

5.1.2 Temperature probe

- Built-in temperature probe for sample monitoring.

5.1.3 Spindles

- The instrument supplied with a standard spindle set constructed of stainless steel.
- Additional spindle options are available in stainless steel or Teflon coating for increased corrosion resistance
- An optional spindle rack makes a convenient storage “bench” and allows easy and quick access to all spindles.

5.1.4 Spindle rack

- The instrument with handy spindle rack for standard spindles.
- Allow for quick and easy access.

5.1.5 Viscosity standards

- The instrument with a viscosity standard to check the accuracy of viscometer.
- Standards are a traceable part of calibration and verification for the instrument. Fluids at 25ºC Qty.: 500 ml (Viscosity values: 5 cps & 12500 cps)

5.2 Identification number and location:

Equipment Name	**Identification Number**	**Location**
Viscometer	…….	Instrument room

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 injectable

5.5 Construction:
Not Applicable

5.6 Capacity:
The Viscometer must be capable for routine laboratory analyses as well as those involved in research and development.

5.7 Electrical construction:
Not applicable

5.8 Control parameters:
Speed control in rpm, No. of speed, Min. viscosity, Max. Viscosity, measurement accuracy, Repeatability.

5.9 Acceptable tolerance for control parameters:

Speed Control in rpm	: 0.01 to 200 rpm
No. of speed	: 54 speeds
Min. viscosity	: 3 cps
Max. Viscosity	: 320 M cp.
Measurement accuracy	: 1%
Repeatability	: 0.2%

5.10 Type of control System:

Selected report format for complying with GLP requirements.
Full GLP capability
Compatible with all accessories
Automatic data collection.
Auto zero function to ensure measurement
Easy-to-use keypad for simple selection of test parameters.

5.11 Feasible parameters to be set:

Selection of spindle, RPM, Name of users, Name of sample for analysis etc.

5.12 Parameters to be indicated by control systems:

1. Continuous display of: Viscosity (cP or mPa^{-s}), Temperature, shear rate, shear stress, % torque, spindle.

2. Time and date formatting.
3. Formatting Format for recording data with company's name in header.

5.13 Available utilities:

Utilities required for electric connection can be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

The instrument measuring technique must comply to pharmacopoeial requirement of USP/BP/ph.Eur

5.16 Delivery Address:

……..

6.0 Safety:

Proper equipment earthing shall be provided.

7.0 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing will be provided that includes:

- Consumable wear parts
- Parts that are easily broken
- Parts that 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 via telephone for a period of 5 years following the completion of commissioning.

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:

USP/BP/In house