



USER REQUIREMENT SPECIFICATION

Name of Item: Melting Point Apparatus

Protocol No.:.....

Functional Area: Quality Control

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1.0 Purpose: To describe the specific requirement of melting point apparatus used for measuring melting point of different compounds.

2.0 Scope: This specification is applicable to the melting point apparatus to be installed at quality control laboratory in analytical and section.

3.0 System Description: Viscometer shall be used for determining the viscosity of the raw materials, finished products and in process samples. The viscosity determination is one of the important tests during formulation development. This test is used in the in process sample checks to know the final behavior of the sample. To maintain standard of quality in all the products and uniformity; viscosity determination test shall be carried out. The viscosity determination shall be carried out on liquid formulation samples like clear liquids, suspension, ointment, gel etc. Additional features of the instrument shall also be considered before placing the order.

The general requirement for viscosity measuring apparatus shall be as under:

3.1 Can be operated as stand alone system as well as through software. If stand alone it should be capable of measuring the viscosity as on screen display.

3.2 Viscosity measurement from 15 cps to 6,000,000 cps. It should have variable speed function for measurement of viscosity.

3.3 Provision for measurement of low viscosity samples through special attachment or through built in system.

3.4 Provision for measurement of viscosity of ointment, cream, gel through special arrangement or through built in system.



PHARMA DEVILS
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3.5 Provision for maintain of temperature of the system as a built in feature or provision for attachment of additional unit for temperature maintenance.

3.6 It should have good reproducibility and accuracy.

3.7 The manufacturer/ supplier should provide complete documentation for validation and calibration of the equipment.

3.8 After sales service back up should be from approachable distance so as to minimize breakdown time, if any.

4.0 Documentation: Supplier/Manufacturer shall provide the following document.

- Test and guarantee certificates.
- Qualification (DQ, IQ, OQ, PQ) documentation
- Calibration standards.
- Operator's manual

5.0 Other Considerations: The manufacture/ supplier shall have the commonly used spares in stock. If not, the manufacture/ supplier shall have the provision to arrange at the earliest. During installation of the equipment the manufacturer/ supplier shall explain the general maintenance procedure for the equipment to the Engineering section and general instructions to the analysts for usage of the equipment.

Prepared By:
Date:

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