USER REQUIREMENT SPECIFICATION (URS)

FOR

MELTING POINT APPRATUS

Department : Quality Control

URS no. : ……..

Supersede : Nil

USER REQUIREMENT SPECIFICATION

Name of Item: Melting Point Apparatus	**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 Melting point apparatus is:
To define the requirement for selection of Melting point apparatus 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 Melting point apparatus to be procured for quality control lab 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 Melting point shall have following components.

- Micro controller
- Fan
- Detection
- Thermo mode
- Monitor screen

The detail description of the components is as follows;

5.1.1 Micro controller

- The instrument have micro controller based for determining melting range of white as well as coloured samples in powdered form.

5.1.2 Fan

- The instrument has an in-Built fan facility for fast cooling.

5.1.3 Detection

- The instrument should have automatically detected by photo sensing and the temperature is locked and display as per pharmacopoeia.

5.1.4 Thermo mode

- The instrument should have automatically detected by photo sensing and the temperature is locked and temperature is display by giving correction for heating rate-thermodynamic evaluation.

5.1.5 Monitor screen

- The instrument should have Monitor screen, a magnified image of the sample can be observed.
- The effect of heat no the sample can be clearly seen.
- The change in physical appearance of the sample with reference to temperature is recorded and the start of melting and end of melting are determined automatically.

5.2 Identification number and location:

Equipment Name	**Identification Number**	**Location**
Melting point apparatus		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 pharmaceutical raw materials

5.5 Construction:
Not Applicable

5.6 Capacity:
Not applicable.

5.7 Electrical construction:
Not applicable

5.8 Control parameters:
Control, Temperature range, Temperature repeatability, Heating rates, Maximum cooling time, Accuracy of detection of melting temp., sampling, Display, Program storage.

5.9 Acceptable tolerance for control parameters:

Control	:	Micro controller-based (Advanced version of microprocessor)
Temp. range	:	Ambient to 350°C
Temp. repeatability	:	0.1°C
Heating rates	:	0.2°C/min, 0.5°C/min, 1.0°C/min, 2.0°C/min, 3.0°C/min, 6.0°C/min, 12.0°C/min.
Max. cooling time	:	From 350°C to ambient approx : 30 min.
Accuracy of detection of melting temp.	:	A) Ambient +5° C to 200°C - ±0.5°C

B) 200º C to 300ºC - ±0.8ºC
C) Above 300ºC - ±1.4ºC

Sampling : A) Sample size – Approx 5 mg.
B) Sample Holder i) Glass slide ii) Glass capillary tube with one end sealed

Display : Monitor to view magnified image of sample

Program storage : Approx 20 methods with parameter

5.10 Type of control System:

Selected report format for complying with GLP requirements.
Report giving parameter and result of last run.
Report of program parameter for method.
Error indication helps user to trace the problems.
Precise temperature control for repeatable results.
Specially designed capillary eject mechanism for easy removal of broken capillary.
Software must supply as standard and allows to control.
Full GLP capability

5.11 Feasible parameters to be set:

Name of users, Name of sample for analysis, set temperature etc.

5.12 Parameters to be indicated by control systems:

1. Run no., Sample name and sample no., Melting point or Melting range etc.
2. Time and date formatting.
3. Formatting Format for recording data with company's name in header.

5.13 Available utilities:

1. Utilities required for electric connection can be provided.
2. Reagent for Calibration can be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

The apparatus shall comply with GLP requirements.

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 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:

Unite states pharmacopeia, British pharmacopoeia, In house