



**PHARMA DEVILS**  
QUALITY CONTROL DEPARTMENT

**USER REQUIREMENT SPECIFICATION**

**Name of Item:** Melting Point Apparatus

**Protocol No.:**.....

**Functional Area:** Quality Control

**Page No.:** 1 of 7

**Name of Equipment:** Melting Point Apparatus

**Document Reference Number:** .....

**Effective Date:** .....



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**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.

<b>Prepared by</b>	<b>Signature</b>	<b>Date</b>
<b>Checked By</b>	<b>Signature</b>	<b>Date</b>
<b>Reviewed By</b>	<b>Signature</b>	<b>Date</b>
<b>Approved By</b>	<b>Signature</b>	<b>Date</b>



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**2.0 Table of Content:**

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**3.0 INTRODUCTION:**

This document is generated for the purpose of specifying the user requirements for the melting point apparatus.

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

The melting point apparatus shall be located at wet lab area of Quality control area.

Melting point apparatus gives the moisture content of sample.

The melting point apparatus shall be interfaced with following components.

1. Magnifier
2. In built magnetic stirrer
3. Electronic controller
4. Silicon oil bath
5. Mains cord

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

The unit shall be feasible to be installed in the current building facility.

**4.0 OVERVIEW DEFINITION:**

**4.1 The melting point apparatus shall have the following features:**

- 4.1.1. The melting point test apparatus is used to find out the melting point samples. The Instrument is designed to meet the specifications of USP, BP, EUR and IP
- 4.1.2. The melting point apparatus should have built in magnetic stirrer.
- 4.1.3. The melting point apparatus should have a pilot lamp magnifier.
- 4.1.4. The melting point apparatus should have a digital temperature indicator.
- 4.1.5. The melting point apparatus should have silicon oil both and silicon oil bath should be made of special glass beaker having capacity about 200 ml.
- 4.1.6. The melting point apparatus should have a oil immersion heater.

**4.2 The melting point apparatus shall be used primarily for:**

Melting point apparatus is used for the malting point & melting range of samples.



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**4.3 Technical Specifications:**

- 4.3.1 Range** : From 2<sup>0</sup>C above Room Temperature to 300<sup>0</sup>C.
- 4.3.2 Temperature Readability** : 0.1<sup>0</sup>C
- 4.3.3 Silicon Oil Bath** : Special Glass beaker having capacity about 200 ml.
- 4.3.4 Temperature Sensor** : Highly sensitive with digital display.
- 4.3.5 Accuracy** : 0.3%.

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

- 4.4.1 Room Temperature** : 24± 2 °C
- 4.4.2 Relative Humidity** : NMT 55 %

**4.5 Base Utilities Available:**

- Electrical** : **Single Phase, 230V ± 10 % 50 HZ**
- Magnetic stirrer** : Silicon oil bath with inbuilt magnetic stirrer

**5.0 OPERATIONAL REQUIREMENTS:**

**5.1 OPERATION:**

The melting point apparatus shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental standpoint.

**5.2 POWER FAILURE/RECOVERY:**

In the event of a power failure, the system will stop automatically and will require operator intervention to re-start.

**5.3 SAFETY FEATURE:**

The system shall be stop safely in emergency.

**5.4 ALARMS AND WARNINGS:**

The Melting point apparatus shall have alarm after the completion of the test.



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**6.0 SALIENT FEATURES:**

**6.1 COMPATIBILITY AND SUPPORT**

**ELECTRIC CONTROL:**

Melting point apparatus should consist of electrical on / off switch for operation.

**UTILITIES**

The Supplier shall specify utility requirement. The User shall ensure that the utilities are available.

**6.2 MATERIAL OF CONSTRUCTION:**

**Base frame** : SS 304

**6.3 Instruments & controls** : Programmable controller

**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 Melting point apparatus with all options, equipment, and the documentation listed below shall be delivered to Client Site.

Delivered 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



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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