



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Melting Point Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Operation & Calibration of Melting Point Apparatus.

2.0 SCOPE:

This SOP is applicable to carry out Melting Point test of material in the Quality Control Department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION(S):

Melting point: It is the temperature at which a solid melts.

5.0 PROCEDURE:

Make: Campbell Electronics , Model: Thermonik

5.1 Operation:

5.1.1 Ensure that instrument is clean and free from dust.

5.1.2 Check the calibration status of instrument and thermometer.

5.1.3 Switch 'ON' the mains.

5.1.4 Loosen the right side screw of the glass container holder and open it fully on its hinges towards left side.

5.1.5 Hold the neck of the oil glass container in the center of the holder and close the holder so as to hold it firmly.

5.1.6 A small triangular platform for testing capillaries is also fixed to these rods, lift the teflon cover and pour around 125 ml of silicon oil.

5.1.7 The level of silicon oil should be 1/4 above the capillary resting platform.

5.1.8 Insert the angular point of the clip in the hole of teflon cover to hold in neck firmly.

5.1.9 Lower down the meter slowly so as to rest it on the lower collar on the motor carrying rod.



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Melting Point Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.1.10 Stirring blade should not touch to the side of glass container. This is checked by rotating the stirrer by hand.
- 5.1.11 Insert the thermometer of the proper range in the thermometer hole.
- 5.1.12 Switch on stirrer & heater of instrument.
- 5.1.13 With voltage regulator, control the temperature so that rise in the temperature near the melting point is gradual (1 degree per minute). Note the temperature at when samples form droplets.
- 5.1.14 To check the boiling point of the liquid fill the boiling point tube with the liquid of which boiling point is to be checked inserting a capillary in the upside down position.
- 5.1.15 Record the activities in the instrument log book.

5.2 Calibration:

- 5.2.1 Operate the instrument as mention in the above procedure.
- 5.2.2 Use glass capillary tube which is open at one end and seal at other end with internal diameter of 1.4 to 1.7 mm and length of 50 to 60 mm fill sufficiently quantity of the given powder to form a compact column about 3 mm height.
- 5.2.3 Keeping the start temperature 3 degree per minute, lower the temperature near the expected melting point and scan at the rate of 1 degree per minute for standard substances (Vanillin , Benzoic Acid, Sulphanilamide, Acetanilide, Caffeine) and record in Annexure - I
- 5.2.4 Tolerance - Vanillin : 81°C to 83°C
Benzoic Acid : 121°C to 123 °C
Sulphanilamide : 164.5 °C to 166.5°C
Acetanilide : 114 °C to 116°C
Caffeine : 234°C to 237°C
- 5.2.5 Frequency : Quarterly
- 5.2.6 If instrument is out of calibration, affix "UNDER MAINTENANCE" label and call for service engineer.
- 5.2.7 Note calibration activity in the instrument log book.

5.3 Precaution:

- 5.3.1 Apparatus should not be ON unless glass container is filled with silicon oil.
- 5.3.2 The level of the silicon oil should be about 1/4" above the capillaries resting platform.



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Melting Point Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.3.3 Switch off the instrument after temperature come down near by 40°C.

6.0 ABBREVIATION (S):

mm - mili meter

ml – milli litre

QCD – Quality Control Department

SOP – Standard Operating Procedure

NA – Not Applicable

7.0 REFERENCE(S):

NA

8.0 ANNEXURE (S):

Annexure - I: Calibration Record of Melting point apparatus.

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

ANNEXURE I

--	--



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Melting Point Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Calibration Record: Melting Point Apparatus			
Location		Model No.	
Make	Campbell	Identification No.	
Calibration Done On		Calibration Due On	
Reference SOP No.:			Page No. : 4 of 1

Thermometer ID No. 1. -----

2. -----

S.No.	Reference Material	Batch/ Lot no.	Observed Melting point	Limit	Remarks.
1.	Vanillin			81°C to 83°C	
2.	Benzoic Acid			121°C to 123°C	
3.	Sulphanilamide			164.5°C to 166.5°C	
4.	Acetanilide			114°C to 116°C	
5.	Caffeine			234°C to 237°C	

Remarks: The Instrument Calibration **Complies / Does Not Comply.**

Calibrated By: Date:	Checked By: Date:
---------------------------------------	------------------------------------