



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

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

1.0 OBJECTIVE:

To lay down procedure for Operation, Cleaning and Calibration of Melting Point Apparatus.

2.0 SCOPE:

This SOP is applicable for operation, cleaning and calibration of Melting Point Apparatus (Make: Veego, Model: VMP - CM).

3.0 RESPONSIBILITY – Execution- Executive QC
Checking -Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 OPERATING PROCEDURE

5.1.1 Switch ON the instrument.

5.1.2 Press the “MENU START” key and “display shows 1- TEST, 2-VALIDATION, 3- UNKNOWN, 4- UTILITY”.

5.1.3 “ENTER <1- TEST>

5.1.4 Enter the Product ID and BATCH NO.

5.1.5 Insert the capillary filled with sample in the Oil chamber.

5.1.6 Uncover and set the lens of camera inserted in front of Oil chamber so that it can make easy to visualize the melting of capillary filled with sample.

5.1.7 Press “Record Next” key. Set the recording temperature for the sample by mode “Enter Melting SP: ,Speed : ”

5.1.8 Press START to run.

5.1.9 For <2-VALIDATION>, ENTER “BATCH NO.”

5.1.10 For <3- UNKNOWN> , ENTER “UNKNOWN ID RATE”

5.1.11 For <4- UTILITY > , ENTER “PASSWORD”

5.1.12 After Completion of the test take out the print of the test.

5.1.13 Switch off the Instrument , cover the lens of the camera.

5.2 CLEANING PROCEDURE

Frequency: Daily or after each use.

5.2.1 Clean the front part of the instrument .

5.2.2 Wipe out any material in the capillary / sample holder assembly by means of tissue paper.

5.2.3 Clean all the accessories(visualising camera lens) with tissue paper after analysis .



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5.2.4 Clean the outer surface of the instrument with dry cotton cloth.

5.3 CALLIBRATION PROCEDURE

Frequency: Once in a month.

5.3.1 Dry the reference standards before use as given below:

a) Vanillin, Sulfanilamide and Caffeine - Dry over Silica gel for 16 hours in a desiccator.

5.3.2 Fill the beaker with silicon oil upto the mark and check the thermometer (Use appropriate range of Calibrated thermometers).

5.2.3 Switch on the power supply.

5.2.4 Start the stirring and press "Start". Adjust the heating rate to 3°C per minute.

5.2.5 Fill the dried reference standard into a capillary tube with one end sealed (ID=0.8 to 1.2 mm) after powdering it, to the height of 3-4 mm and compact it with mild tapping.

5.2.6 Insert the capillary tube when the temperature reaches 10 deg.C below the expected melting point. Reduce the heating rate to 1-2°C per minute near the melting point of the reference standard.

5.2.7 Note down the temperature at which the reference standard collapses definitely against the sides of the capillary tube. Also note the temperature at which the reference standard becomes liquid throughout. These two temperature give the melting range of the reference standard.

5.2.8 Repeat the above procedure for all the reference standards.

5.2.9 Apply the necessary correction to the observed values against the actual values.

5.2.10 Mark the thermometer with Identification number and date of calibration.

5.2.11 ACCEPTANCE CRITERIA :

S.No.	Reference standards(USP)	Melting Range(°C)
1.	Vanillin	81 - 83
2.	Sulfanilamide	164.0 - 165.7
3.	Caffeine	235.4 - 237.8

6.0 SAFETY & PRECAUTIONS

Not Applicable



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7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

No. : Number

QC : Quality Control

° : Degree Celsius



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ANNEXURE-I CALIBRATION RECORD OF MELTING POINT APPARATUS

PERFORMANCE DATE	DATE OF LAST PERFORMANCE DONE	NEXT DUE FOR PERFORMANCE

INSTRUMENT DETAILS		
INSTRUMENT NAME	INSTRUMENT MAKE	INSTRUMENT IDENTIFICATION NO.

OBSERVATION				
S.No.	Reference Standard	Melting Range	Observed Melting Point	Remarks

Remarks : Satisfactory/Not Satisfactory

CONCLUSION	
INSTRUMENT WORKING SATISFACTORY	INSTRUMENT NOT WORKING SATISFACTORY

PERFORMED BY			CHECKED BY		
NAME	SIGN	DATE	NAME	SIGN	DATE