



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation, Cleaning and Calibration of Osmometer	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down procedure for operation, cleaning and calibration of Osmometer.

2.0 SCOPE:

This SOP is applicable for operation, cleaning and calibration of Osmometer manufactured by Advanced instrument Inc. Model No. 3250.

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

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 General Cleaning

5.1.1 Clean the exterior of the instrument with a clean dry cloth.

5.1.2 To clean the interior of the instrument, ensure that the power to the instrument is switched OFF.

5.1.3 Clean it with a dry cloth and if required, clean with a cloth dipped in mild detergent solution followed by wiping with a clean dry cloth.

5.2 OPERATION

5.2.1 Switch on the instrument from the main power supply and a power switch provided in the rear of the instrument.

5.2.2 Gently wipe the probe, stir/freeze wire, mandrel and the top of the freezing chamber with a soft, lint free, non-ionic tissue paper dampened with distilled water to remove anything that might contaminate the sample to be tested.
Select a clean sample tube and put it inside freezing chamber.

5.2.3 Pipette out 200 μ L of sample with the help of a micropipette and transfer in to the sample tube.

5.2.4 Press start. The instrument will automatically run diagnostic test where it cools the freezing chamber and completes a series of internal diagnostic checks.

5.2.5 When display read Osmometer ready. Press start, enter sample ID (maximum up to 13 digits), Press ENTER, and then Press START.

5.2.6 After end of the test the display reads “Osmolality xxx mOsm “

5.2.7 Wipe the probe, stir/freeze wire with tissue paper.

5.3 CALIBRATION



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Frequency of calibration

For calibration at Low Range -Once in six months and after each maintenance job.

For Calibration at High Range-To be done only when required as per sample

The instrument can be calibrated at two ranges with two-calibration standard solution.

Low range : 100 and 1500 mOsm/kg H₂O

High range : 1500 and 3000 mOsm/kg H₂O

Calibration at Low range :

- 5.3.1 At Osmometer ready press CALIB. The CALIB key will light and the display will quickly change to "Calibration" then prompt you for the first calibration standard
- 5.3.2 Pipette out 200 μ L of calibration standard (100 mOsm/kg H₂O) with the help of micropipette and transfer in to the sample tube.
- 5.3.3 Press START .The display reads "Osmolality xxx mOsm " such a three sample are required at the first calibration level of the low range(100 mOsm/kg H₂O).Fill the observation as per Annexure I
- 5.3.4 Pipette out 200 μ L of calibration standard (1500 mOsm/kg H₂O) with the help of a micropipette and transfer in to the sample tube.
- 5.3.5 Press START. Six samples are required at the second calibration level of the low range (1500 mOsm/kg H₂O) and at each calibration level of the High range.
- 5.3.6 When the six calibration tests in second calibration level are completed, the display reads "Calibration Complete".

Calibration at High range :

- 5.3.7 For calibration at high range change the range from menu option of "select range" press START to display range, select high range and press ENTER.
- 5.3.8 Repeat the same procedure as described under Low range except to use six sample at each calibration level. Fill the observation as per Annexure II

Acceptance criteria

Expected Value	Expected Range
100 mOsm/kg H ₂ O	98-102 mOsm/kg H ₂ O
1500 mOsm/kg H ₂ O	1492.5-1507.5 mOsm/kg H ₂ O
3000 mOsm/kg H ₂ O	2985-3015 mOsm/kg H ₂ O



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6.0 SAFETY & PRECAUTIONS:

- 6.1 Always wipe off splashed liquids from the instrument surface.
- 6.2 Always keep a sample tube inside the freezing chamber, to avoid entry of dust dirt and debris inside the freezing chamber.
- 6.3 Wipe the stir/freeze wire with tissue paper after every test .
- 6.4 Use the same sample size consistently for repeatability of test.
- 6.5 Regularly replace the heat transfer fluid, when the liquid level is below the replace line on the bottle label.
- 6.6 Always use fresh sample tubes.

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

Annexure I : Format of Calibration Report {Low Range}

Annexure II : Format of Calibration Report {High Range}



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ANNEXURE -I CALIBRATION RECORD OF OSMOMETER {Low Range}

PERFORMANCE DATE	DATE OF LAST PERFORMANCE DONE	NEXT DUE FOR PERFORMANCE

INSTRUMENT DETAILS		
INSTRUMENT NAME	INSTRUMENT MAKE	INSTRUMENT IDENTIFICATION NO.

OBSERVATION

Calibration Of Osmometer at Low Range

S.No.	Standard	Observed Reading	Acceptance Criteria
1.	100 mOsm		98 – 102 mOsm/ kgH ₂ O
2.	100 mOsm		98 – 102 mOsm/ kgH ₂ O
3.	100 mOsm		98 – 102 mOsm/ kgH ₂ O
	MEAN		98 – 102 mOsm/ kgH ₂ O

Remarks : Satisfactory/Not Satisfactory

S.No.	Standard	Observed Reading	Acceptance Criteria
1.	1500 mOsm		1492.5 – 1507.5 mOsm/kgH ₂ O
2.	1500 mOsm		1492.5 – 1507.5 mOsm/ kgH ₂ O
3.	1500 mOsm		1492.5 – 1507.5 mOsm/ kgH ₂ O
4.	1500 mOsm		1492.5 – 1507.5 mOsm/ kgH ₂ O
5.	1500 mOsm		1492.5 – 1507.5 mOsm/ kgH ₂ O
6.	1500 mOsm		1492.5 – 1507.5 mOsm/ kgH ₂ O
	MEAN		1492.5 – 1507.5 mOsm/ kgH ₂ O

Remarks : Satisfactory / Not Satisfactory



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CONCLUSION	
INSTRUMENT WORKING SATISFACTORY	INSTRUMENT NOT WORKING SATISFACTORY

PERFORMED BY			CHECKED BY		
NAME	SIGN	DATE	NAME	SIGN	DATE

Calibration done by :

Date :

Checked by :

Date :



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ANNEXURE -II CALIBRATION RECORD OF OSMOMETER {High Range}

PERFORMANCE DATE	DATE OF LAST PERFORMANCE DONE	NEXT DUE FOR PERFORMANCE

INSTRUMENT DETAILS		
INSTRUMENT NAME	INSTRUMENT MAKE	INSTRUMENT IDENTIFICATION NO.
OBSERVATION		

Calibration Of Osmometer at High Range

S.No.	Standard	Observed Reading	Acceptance Criteria
1.	1500 mOsm		1492.5 – 1507.5 mOsm/kgH ₂ O
2.	1500 mOsm		1492.5 – 1507.5 mOsm/kgH ₂ O
3.	1500 mOsm		1492.5 – 1507.5 mOsm/kgH ₂ O
4.	1500 mOsm		1492.5 – 1507.5 mOsm/kgH ₂ O
5.	1500 mOsm		1492.5 – 1507.5 mOsm/kgH ₂ O
6.	1500 mOsm		1492.5 – 1507.5 mOsm/kgH ₂ O
	MEAN		1492.5 – 1507.5 mOsm/kgH ₂ O

Remarks: Satisfactory/Not Satisfactory

S.No.	Standard	Observed Reading	Acceptance Criteria
1.	3000 mOsm		2985.0-3015.0mOsm/kgH ₂ O
2.	3000 mOsm		2985.0-3015.0mOsm/kgH ₂ O
3.	3000 mOsm		2985.0-3015.0mOsm/kgH ₂ O
4.	3000 mOsm		2985.0-3015.0mOsm/kgH ₂ O
5.	3000 mOsm		2985.0-3015.0mOsm/kgH ₂ O
6.	3000 mOsm		2985.0-3015.0mOsm/kgH ₂ O
	MEAN		2985.0-3015.0mOsm/kgH ₂ O

Remarks: Satisfactory / Not Satisfactory

CONCLUSION	
INSTRUMENT WORKING SATISFACTORY	INSTRUMENT NOT WORKING SATISFACTORY



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PERFORMED BY			CHECKED BY		
NAME	SIGN	DATE	NAME	SIGN	DATE

Calibration done by : _____ **Date:** _____

Checked by : _____ **Date:** _____