TAmedics

LIFE SCIENCE SWITZERLAND

OSMOLALITY · FREEZING POINT DEPRESSION

Osmolality in 90 seconds. From 50 µl.

The reference method for pharmacopoeial osmolality testing, on a benchtop instrument that needs no refrigerant and no compressor. Supplied, installed, calibrated and serviced by TAmedics, with one contact from quotation to maintenance.



Model OSM-BF3

faster. • *more direct.* • *more personal.*

Freezing Point Osmometer Model OSM-BF3

LIFE SCIENCE · TAMEDICS PORTFOLIO

BUILT FOR PHARMACEUTICAL AND BIOPROCESS LABORATORIES

The reference method, on your own bench

Ph. Eur. 2.2.35 and USP <785> define osmolality by freezing point depression. The instrument performs exactly that measurement: pipette the sample, the measuring head lowers automatically, and the result is stored with a time stamp and printed. Two-point or multi-point calibration, depending on your QC concept.

01

Under 90 seconds

Pre-cooling in three minutes or less, then every measurement in under 90 seconds. Long release series stay short.

02

Only 50 µl of sample

50 to 100 µl is enough. Valuable where material is scarce: formulation screening, stability pull points, residual volumes.

03

Peltier, no refrigerant

Dual semiconductor cooling without refrigerant or compressor. Quiet, low heat load and no service gas, which matters in a controlled area.

04

Traceable by design

Audit trail, four-level password-protected user management, 50,000 time-stamped records and an integrated printer.

<90 s	50 µl	3000 mOsm	±2 mOsm
PER MEASUREMENT	SAMPLE VOLUME	PER KG H_2O RANGE	ACCURACY TO 400

WHERE IT EARNS ITS PLACE

Release testing	Parenterals, infusions, ophthalmics, dialysis solutions
Upstream	Cell culture media and feeds, batch and perfusion control
Downstream	Buffer preparation and dilution verification
Formulation	Excipient screening, tonicity adjustment, stability studies
Pilot plant	In-process control close to the suite

WHY FREEZING POINT

Freezing point depression measures the total concentration of dissolved particles directly, without assumptions about the solute. It is the method the pharmacopoeias describe, which keeps your method transfer, your validation and your inspector on familiar ground.

APPLICATIONS AND SPECIFICATION

One measurement, four places it answers a question

RELEASE TESTING

Parenteral products

Osmolality is a specified attribute for injectables, large volume parenterals and ophthalmic preparations. Measuring in house removes a contract laboratory turnaround from the release path.

BIOPROCESS

Media and feed control

Osmolality tracks the concentration of the culture environment and is a routine in-process parameter in fed-batch and perfusion operations, where it is read alongside glucose and lactate.

DOWNSTREAM

Buffer verification

A quick check that a prepared or diluted buffer matches its recipe, before it reaches a column. Cheaper than finding out afterwards.

DEVELOPMENT

Formulation and stability

Tonicity adjustment during formulation, and an orthogonal readout at stability pull points, from the small volumes development work tends to leave over.

SPECIFICATION

Method	Freezing point depression
Measuring range	0 to 3000 mOsmol/kg H_2O
Resolution	1 mOsmol/kg H_2O
Sample volume	50 µl (50 to 100 µl)
Pre-cooling / measurement	≤ 3 min / < 90 s
Accuracy	± 2 mOsmol/kg up to 400 mOsmol/kg ≤ 1 % above 400 mOsmol/kg
Repeatability	RSD ≤ 1 % at 300 mOsmol/kg
Cooling	Dual Peltier, no refrigerant, no compressor
Readout	Freezing point, osmolality, ratio
Data	50,000 time-stamped records, audit trail, four user levels, integrated printer
Power	AC 220 V ± 10 %, 65 W
Dimensions / weight	372 × 264 × 448 mm / 13 kg

Technical data according to the manufacturer data sheet, subject to change.

IN A REGULATED ENVIRONMENT

- **Records that survive an audit:** every result carries a time stamp, the audit trail records changes, and user levels are password protected.
- **Calibration you can trace:** two-point or multi-point calibration against certified reference solutions, documented on delivery and at every service visit.
- **Qualification support:** we provide installation and operational qualification documentation and perform the on-site execution with your QA.
- **No service gas:** semiconductor cooling removes refrigerant handling from your maintenance plan.

Computerised system compliance, including 21 CFR Part 11 and EU GMP Annex 11, is assessed for the system as deployed in your environment. We supply the instrument documentation and support your assessment; we do not certify your process.

WHY BUY IT FROM TAMEDICS

An instrument is quick to order. Keeping it qualified is the work

Most of what an osmometer costs over its life is not the purchase price. It is calibration, consumables, documentation and the day it stops working in the middle of a release series. That is the part we take on.

IN-HOUSE SPECIALISATION

Osmometers are serviced by our own engineers

Not forwarded. Osmometry is one of the platforms our engineers have worked on for years in Swiss laboratories and production sites, with the training and tooling that goes with it.

On site within 24 hours. Corrective service on working days under a service agreement, from our workshop in Schlieren. A call does not become a ticket in a queue abroad.

WHAT A DELIVERY INCLUDES

1

Delivery

Instrument, reference solutions, sample tubes and starting consumables from our Swiss stock.

2

Commissioning

Installation at the bench, first calibration and a documented functional check.

3

Documentation

Declaration of conformity, calibration record, qualification documents and the service report.

4

Training

Hands-on introduction for the operators who will actually run the samples.

SERVICE MODELS

Service Agreement

For instruments in routine QC

- Annual preventive maintenance and calibration
- On-site response within 24 hours
- Consumables planned with your schedule

Calibration Only

For low-throughput instruments

- Scheduled calibration with certified standards
- Documented record for your QA file
- Corrective service on request

On Demand

For projects and peaks

- Corrective service and troubleshooting
- Relocation and recommissioning
- Support during qualification

CONSUMABLES FROM THE SAME SOURCE

Reference solutions	Certified standards for two-point and multi-point calibration
Sample tubes	0.5 ml tubes, standard laboratory consumable
Spare parts	Held in Schlieren for the parts that fail first

One order, one delivery note, one invoice. Swiss laboratories tell us the same thing: they do not want to source an instrument in one place, its standards in another and its service in a third. Everything on this page comes from Schlieren.

Request a quotation or a demonstration

We bring the instrument to your laboratory and measure your own samples. Swiss stock, Swiss service, one contact from quotation to maintenance.

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