Advanced Instruments® Bioprocessing Osmolality Solutions





OsmoTECH® XT

Single-Sample Micro-Osmometer

Best-in-Class Osmolality Performance

NOVA BIOMEDICAL®



Osmolality is Essential to Your Process QC

You need process and quality control to provide confidence that you're developing a quality therapeutic. Testing osmolality gives you that confidence. At key points during process development and manufacturing, osmolality testing is critical—during upstream processing, downstream processing, formulation, and as part of the final product quality check.

Work Confidently with the Advanced Instruments OsmoTECH XT

During this demanding bioproduction process, timing is critical and there are many inherent risks that can impact your final drug product. To have confidence that your therapeutic meets specifications to guarantee optimal critical quality attributes, you need robust and reliable quality control parameters.

The OsmoTECH XT Single-Sample Micro-Osmometer is the perfect instrument for:

- Raw materials QC
- Media and buffer QC
- In-process testing
- Formulation
- Compendial testing
- Final product release

Upstream

Critical lot release test for media production to guarantee quality and consistency.

As processes are scaled up and made more continuous, it's critical to measure cell culture and fermentation osmolality to ensure optimal cell health, drug product quality and yield.

Downstream

Critical in-process and lot-release test for raw materials and process reagents.

Ensures accurate preparation of buffers at a range of concentrations, from low working concentrations to high starting concentrations for in-line dilution systems.

Formulation

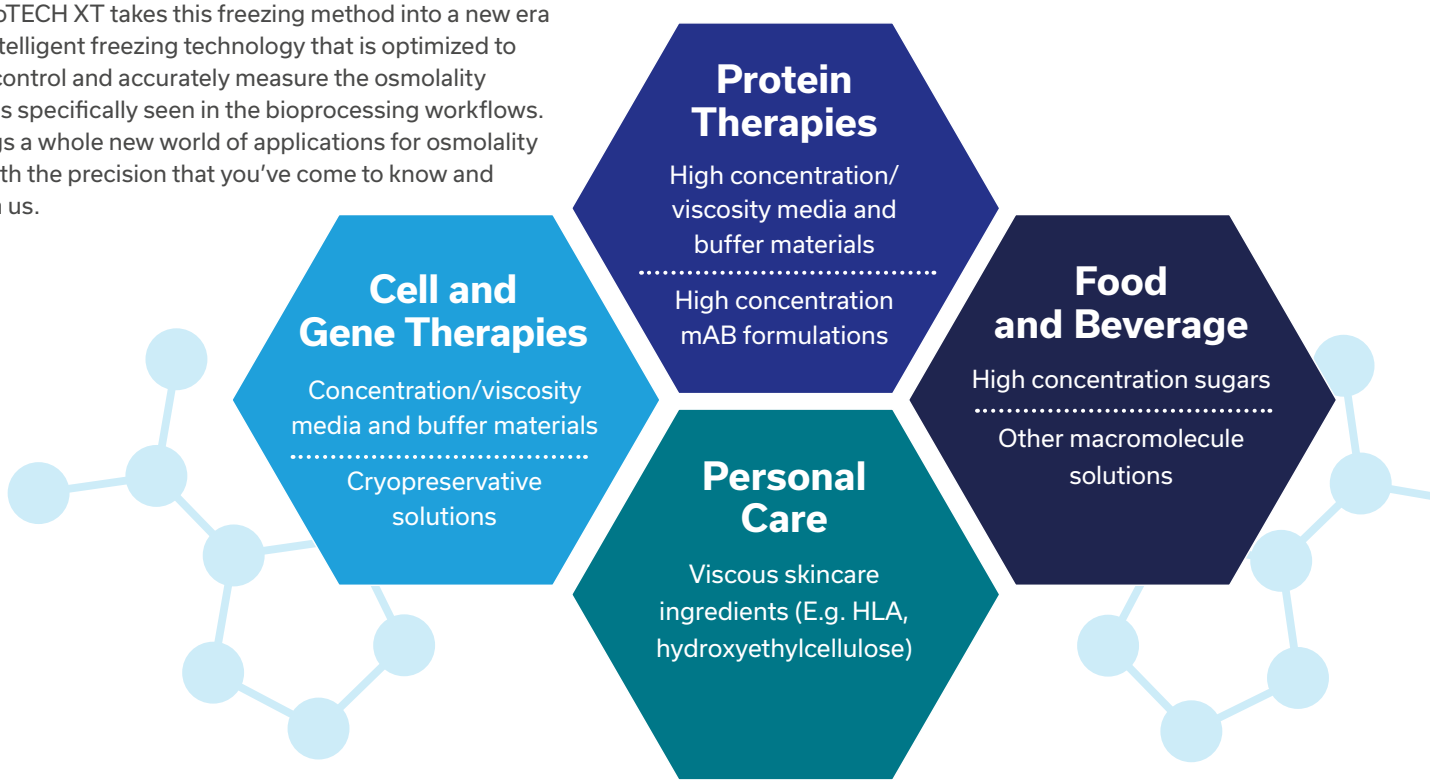
Confirm stability and safety of the drug during storage, reconstitution, and injection. This is particularly important with the addition of stabilizing excipients and/or cryopreservatives.

Confirm product quality and final release criteria by testing osmolality to ensure product is within specific range.

Experience the Superior Performance

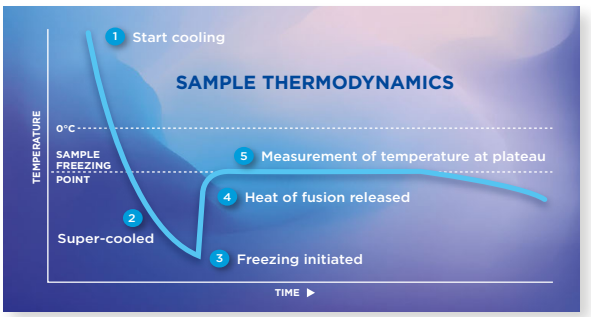
Our osmometers utilize the industry-preferred freezing point depression method to determine the osmolality of an aqueous-based solution. When a solute (particles) is dissolved in a solvent (water), the freezing point of that solution is lowered compared to that of the solvent alone. As more solute is added, the freezing point decreases further. Therefore, by precisely measuring the freezing point of the solution, the osmolality (i.e. concentration) can be determined.

The OsmoTECH XT takes this freezing method into a new era with its intelligent freezing technology that is optimized to monitor, control and accurately measure the osmolality of samples specifically seen in the bioprocessing workflows. This brings a whole new world of applications for osmolality testing with the precision that you've come to know and trust from us.



Driven by Intelligence

The OsmoTECH XT gives a truly comprehensive measurement of samples with the ability to freeze complex sample matrices as well as detect osmolality to 4000 mOsm/kg of H_2O. Additionally, the instrument is able to achieve:



- Fast test time
- Consistent reliable results using small sample volume (20 µL)

The intelligent freezing technology works best with solutions that have high osmolality or other complex physical characteristics (such as viscosity). These samples, such as concentrated sugars, proteins, large molecules and oligonucleotides, are commonly seen across the different modalities.

Extended Range of Testing

This Device Offers Osmolality Testing for Extended Sample Types:

High concentration/osmolality—Bioproduction in all areas is seeing a rise in the concentration of solutions, from raw materials and supplies to drug substances and products. With more than twice the osmolality range of its counterparts, the OsmoTECH XT can measure the osmolality of highly concentrated solutions.

High viscosity—The viscosity of bioprocessing solutions may not greatly impact the osmolality, but it can make many analytical measurements challenging. The OsmoTECH XT was designed to accommodate your complex and viscous solutions with great performance.







Sample	Osmo Value (mOsm/kg)	3250	OsmoTECH	OsmoTECH XT
3M Acetic Acid	3200	1	DNF	✓
2M Acetic Acid	2000	✓	✓	✓
1.5M Citrate	2500	1	OOR	✓
2M Citric Acid	3200	1	DNF	✓
1M Citric Acid	1600	✓	✓	✓
2M Phosphoric Acid	3000	✓	DNF	✓
1.5-2.0M Tris	2500	DNF	OOR	✓
Phosphate/Salt Buffer	3000	✓	DNF	✓
2000 Salt Std	2000	✓	✓	✓
3000 Salt Std	3000	✓	DNF	✓
4000 Salt Std	4000	✓	DNF	✓
10% Protein/ Sucrose	350	✓	2	✓
20% Protein/ Sucrose	350	DNF	2	✓
CryoStor® CS5	1400	3	✓	✓
CryoStor® CS10	2800	DNF	OOR	✓

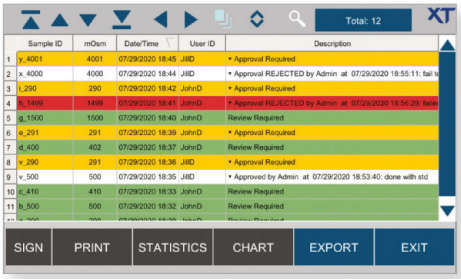
Table: Comparison between osmolality testing and performance across different sample types and instruments. Checkmarks indicate successful freezing of samples with accuracy and precision. Note: Osmolality values listed are approximate and for reference purposes only.

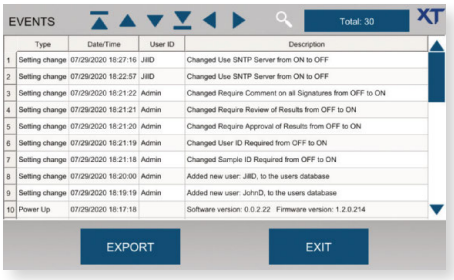
OOR = Out of Range
DNF = Did not Freeze

1. Requires Buzz Point Change
2. Poor precision
3. Inconsistent freezing

Data Tracking and Traceability to Your Workflow Needs

Security features support 21 CFR Part 11 and EU Annex 11 compliance.





- **User Access Level**—Setup the instrument to reflect the hierarchy of your team with three levels - Administrator, Supervisor & Operator.
- **Electronic signature of all results**—Review and approve data electronically on the instrument to ensure traceability and control of all data generated on the instrument.
- **Data Security with user authentication and password**—Require user login for testing and system configuration. You can also manage user access with active directory (LDAP).
- **Unlimited data storage**—We understand your data is valuable and never want to overwrite. Additionally, your data is protected with automatic or manual backup.
- **Complete traceability**—Enable "Require reason for change" and capture additional information to the changes made on the instrument.
- **Complete & Secure Audit Trail**—All the data and events are securely recorded to ensure integrity and compliance.

Effortless Data Management for a Paperless Environment

Peace of mind delivered!

All data can be automatically exported to a network folder in (.pdf or .csv format) via Network Share or LIMS from anywhere.



Seamless data integration and process control with bi-directional capability:

Using OPC-UA connect to lab management and middleware software such as Sm@rtline Data Cockpit® (SDC) and more.

Curious to know how your replicates performed?

Get quick statistics by selecting two or more results in RESULTS menu, and then select "STATISTICS" on the menu.



Compliance with Quality Assurance Demands

Our products are manufactured in an ISO® 9001 and ISO® 13485-registered production site, and their certificates are available on demand. To assist you in following industry requirements, specific documents are also available.

Surpassing all expectations—The OsmoTECH XT is built to exceed your most demanding needs. It is perfectly suited across the low throughput bioprocessing value chain and meets the comprehensive quality and regulatory requirements. The ability to truly support 21 CFR Part 11 and EU Annex 11 compliance with robust data security features is our commitment to help ensure your organization is always compliant.

OsmoTECH XT meets osmolality testing guidelines in the biopharmaceutical industry to control the quality of final products and the materials used to manufacture them as described by the organizations below:

- European Pharmacopeia
- United States Pharmacopeia
- Japanese Pharmacopeia
- Chinese Pharmacopeia

Get Instant Online Access

To view your certificates of analysis for osmolality controls at
https://www.novabiomedical.com/support/certificates-of-analysis/



Advanced Services

You Can Benefit from a Range of Services to Help Your Instrument Operate at Optimum Efficiency Now—and in the Future.

Our certified service engineers follow strict standard procedures, use only genuine parts, and provide a formal service report in line with quality assurance guidelines.

Our full Qualification Program is designed to support laboratory validation procedures. We help bring your instrument online more quickly. Our expert qualification services ensure fast and reliable commissioning of your instrument. The program includes qualification workbooks with IQ and OQ services and requalification services.

Keep your Instrument in Optimal Performance

Get total peace of mind with an Advanced Care service agreement. It includes annual preventive maintenance that keeps your instrument running in top condition and also ensures protection in case of instrument down time.

OsmoTECH XT—Built for Biotech



Optimized Lab Space

Small footprint and integrated consumable shelf for consumables. Consumables are also clean-room friendly!

Large User-Friendly Interface

Like a smartphone, interactive touch screen allows easy access to information.

Experience Widest Range of Osmolality Testing

Say goodbye to dilutions! For the first time ever, measure samples from 0-4000 mOsm/kg.

One-Step Direct Sampling

Positive displacement sampler to help aspirate even viscous sample types.

New Intelligent Freezing Technology

With only 20 µL sample requirement and an optimized cooling engine able to monitor, control and measure even the most complex samples more accurately & precisely.

Maintain Traceability

Integrated barcode scanner helps with sample identification and reduces transcription errors.



Robust & Flexible Data Management

Several ways, including Network share, USB download, Open Protocol communication (OPC), LIS (TCP/IP communication), or an Optional printer.

OSMOTECH XT

Parts and supplies

Part number	Product description
Instrument	
OsmoTECHXT	OsmoTECH® XT Single-Sample Micro-Osmometer
Calibration standards, reference solutions and testing supplies	
SK-TECHXT	Convenience Kit includes: • 2 boxes of 100 sampler tips and chamber cleaners, and 1 plunger wire (XT100) • Reference Solution; Clinitrol 290, 2mL Ampule, Pkg 10 (3MA029) • 0 mOsm/kg Calibration Standard (ten 2-mL ampules) 3MA000 • 500 mOsm/kg Calibration Standard (ten 5-mL ampules) 3LA051 • 1500 mOsm/kg Calibration Standard (ten 5-mL ampules) 3LA151 • 3000 mOsm/kg Calibration Standard (ten 5-mL ampules) 3LA301 • 4000 mOsm/kg Calibration Standard (ten 2-mL ampules) 3MA400 • Osmolality Linearity Set (5 levels) (ten 2-mL ampules) 3LA028

1. Subject to change
2. AI standards and reference solutions. Nova Biomedical completes testing from 0 mOsm/kg sample to 4000 mOsm/kg sample during in-house linearity testing.
3. AI standards and reference solutions Performance at Reference Conditions: 20 °C to 25 °C (68 °F to 77 °F); 40 to 60% relative humidity

Specifications[1]

Sample type	Aqueous solution
Sample volume	20 ±1 µL
Test time	≤150 seconds (typical) for low range ≤190 seconds (typical) for high range
Sample capacity	Single sample
Resolution	1 mOsm/kg H_2O
Range	0 to 4000 mOsm/kg H_2O
Accuracy[2]	±2 mOsm/kg H_2O from nominal value between 0 and 400 mOsm/kg H_2O (1 SD) ±0.5% from nominal value between 400 and less than 1500 mOsm/kg H_2O (1 SD) ±1% from nominal value from 1500 to 4000 mOsm/kg H_2O (1 SD)
Within-Run Repeatability[3]	Standard deviation ≤2 mOsm/kg H_2O between 0 and 400 mOsm/kg H_2O Coefficient of variation ≤0.5% between 400 and less than 1500 mOsm/kg H_2O Coefficient of variation ≤1% from 1500 to 4000 mOsm/kg H_2O
Supported languages	English, Simplified Chinese, French, German, Italian, Japanese, Korean, Russian, Spanish, Turkish
Storage temperature	-20°C to +45°C (-4°F to +113°F)
Electrical voltage	100 to 240 VAC (50/60 Hz)
Power consumption	60 Watts
Dimensions (DxWxH) **Dimensions (DxWxH)**	Not including test kit: 15″ x 14″ x 10″ (38 cm x 36 cm x 25 cm) Including test kit: 15″ x 14″ x 11.5″ (38 cm x 36 cm x 38 cm)
Net weight	5.9 kg (12.9 lbs)
Shipping weight	11.4 kg (25 lbs)
Warranty	One-year limited warranty on workmanship and parts



Optimal performance requires quality test supplies.
Nova Biomedical provides a full line of calibration standards and consumables. These supplies ensure optimal system performance and accurate test results.

NOVA BIOMEDICAL®

Not for patient diagnostic use

CE ETL Intertek 98214 RoHS

To learn more or request a quote, visit: www.novabiomedical.com
Nova Biomedical | 200 Prospect Street | Waltham, MA 02454 USA

MP00097 Rev 5

Nova Biomedical Corporation certifies that the technical features needed for 21 CFR Part 11 and EU Annex 11 compliance are built into OsmoTECH XT. It is your responsibility to implement the necessary controls in your laboratory to comply with 21 CFR Part 11 and EU Annex 11 requirements

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