OSMOTECH

OsmoTECH®

Single-Sample Micro-Osmometer

Because quality control is non-negotiable.

ADVANCED INSTRUMENTS

Osmolality testing - an essential in-process control and quality check for bioprocessing

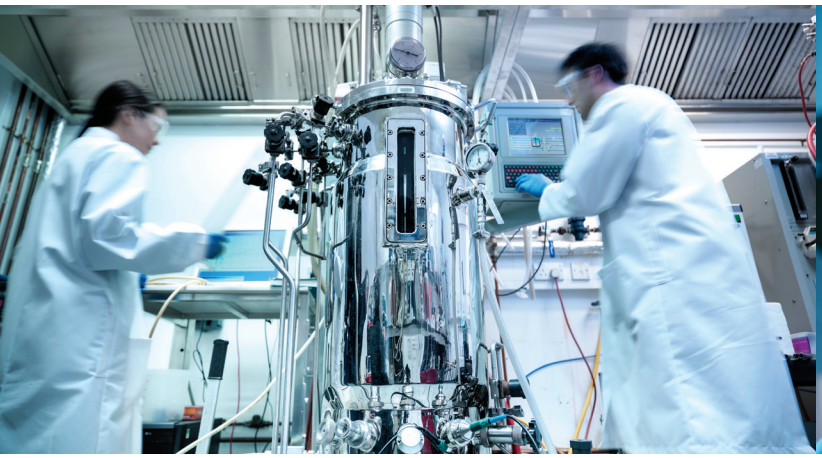
During development of biological drugs or therapeutic molecules, it's important to test osmolality throughout different stages of process development. Osmolality testing helps ensure cell health, in-process reagent quality, and helps reduce the risk of expensive batch failures which can delay delivery of therapeutics to patients.

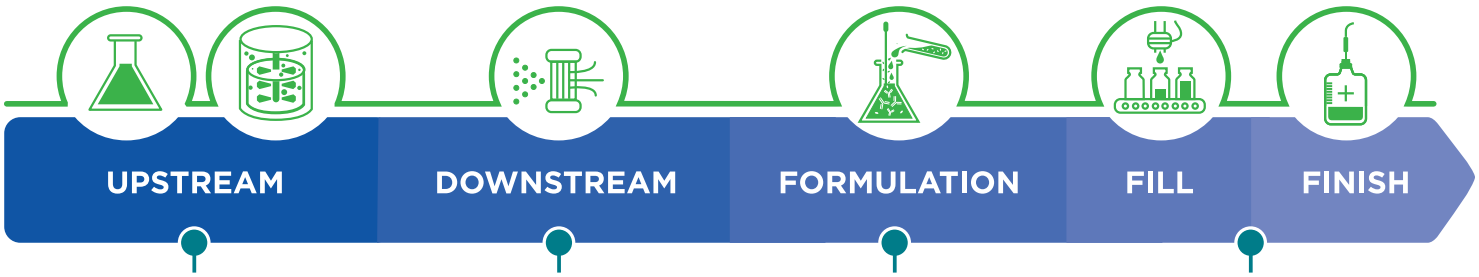
Furthermore, it is essential to create reproducible processes at each stage-- so you can have confidence that you're developing a quality therapeutic. Testing osmolality gives you that confidence. At key points during processing, osmolality testing is critical--during upstream, downstream, and as part of the quality check during formulation and fill.

Ensure process control with OsmoTECH

Leveraging our expertise in osmolality testing, Advanced instrument has designed the OsmoTECH single-sample osmometer. It is an accurate, precise, and easy to use instrument built with the freezing point technology.

To truly meet the unique needs of the biotech industry, the OsmoTECH is enhanced with data management options and data compliance features to seamlessly integrate into the workflow.





Guarantee quality and concentration of raw materials for buffer management.

Ensure precise buffer preparation and maintain proper concentrations during purification and filtration operations for efficient processing.

Safeguard your biologic as it passes through storage, reconstitution and injection.

Ensure that the final product meets compendial quality standards and provide confidence in product stability.

OsmoTECH — Built for Biotech

User-friendly interface

The menu-driven operating system, multi-language capability and touchscreen graphical user interface all make for easy operation

One-step direct sampling

Simply aspirate the sample and load the sampler into the OsmoTECH

Small sample requirement

Just a 20 µL sample volume is needed for sample-limited applications

Maintain traceability

The integrated barcode scanner helps with sample identification and reduces transcription errors

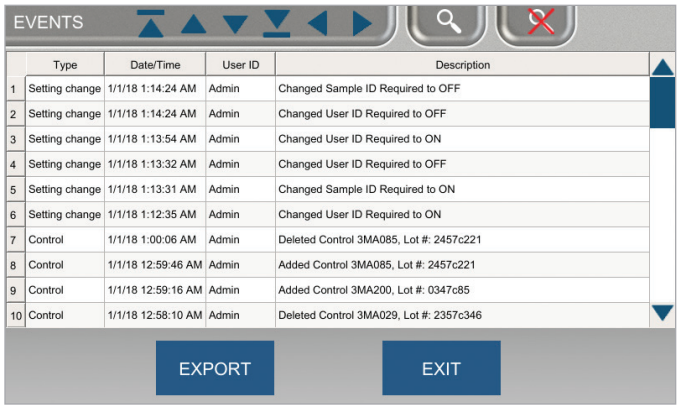
Manage and export data with ease

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

Support compliance. Streamline workflow.

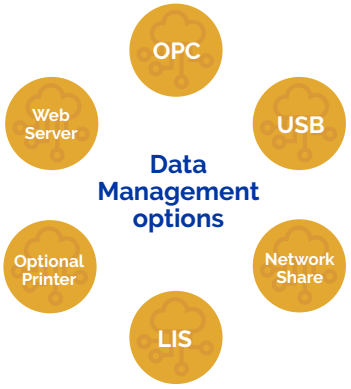
The most data management features of any osmometer on the market

Security features support 21 CFR Part 11 and EU Annex 11 Compliance



- **Three levels of user access:** Set up to reflect the hierarchy of your team
- **Active directory/LDAP:** Align with your IT network to minimize manual input
- **Password protection:** Configurable password to match internal security requirements
- **Pre-expire passwords:** Force password change on first login to ensure maximum security
- **Automatic logout timer:** Keep your data safe during idling
- **Audit trail:** Preserve unlimited results and events
- **Change management:** Require reason for changing settings

Flexible data management options to fit your workflow



- **OPC-UA:** Easily integrate your results into a data management system and batch records
- **PDF or CSV export:** Quickly save data to network folder or USB
- **Database backup:** Protect your data with automatic or manual backups
- **Network time synchronization:** Eliminate the need to manually manage date and time
- **Embedded web server:** Remotely view and manage data for additional walkaway time
- **Results database on/off:** Decide whether results are stored on the system
- **LIMS/LIS:** Effortlessly connects for sample and data tracking
- **Dot matrix printer (optional):** Prevents records from fading
- **Storage:** Unlimited data storage for access.
- **2D barcode scanner:** Eliminate transcription errors

Ensure Maximum Productivity—
IQ/OQ Validation | Installation & Training | Advanced Care Service Agreements

Compliance with Quality Assurance demands

Surpassing all expectations—the OsmoTECH is built to exceed your most demanding needs. It is perfectly suited for mid to high throughput areas across the bioprocessing value chain, thus streamlining efficiency and allowing customers more time to focus on other areas of work. It also helps support compliance within 21 CFR Part 11 and EU Annex 11 with robust data security features that can be easily adapted for your organization's unique structure.

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

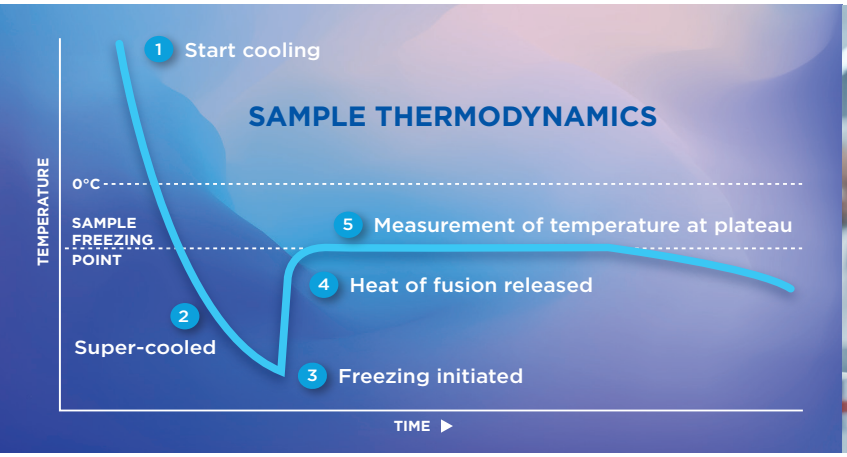
- European Pharmacopeia
- United States Pharmacopeia
- Japanese Pharmacopeia
- Chinese Pharmacopeia

Customize data reporting features to your workflow

OsmoTECH's new and innovative features let you customize testing and data reporting to best fit your workflow and existing structure.

You can:

- Choose from configurable data settings to match your needs as they evolve during R&D, preclinical research, clinical testing and GMP compliance
- Explore several options for data management and connectivity. You can fully integrate data into a centralized system; turn off data connectivity and storage if your process is paper-based; or choose any extent in between



Unparalleled ease of use

OsmoTECH guarantees you a simple and fluid experience:

- Interactive and intuitive touch screen with multi-language capacity
- Color-coding with on-screen messages to let you know the instrument's status
- Arrives factory-calibrated, with no need for routine calibration
- Short start-up time; start testing quickly

Delivers the accurate results you demand

The OsmoTECH utilizes freezing point depression— the gold standard method of testing osmolality. Freezing point depression is preferred by biotechnology labs worldwide because it assures:

- Fast 90-second test time and accurate measurements
- Consistently reliable results using a small sample requirement (20 µL)
- Full characterization of concentration, including volatiles, such as alcohol

Only freezing point osmolality is a truly comprehensive measurement of samples, as it is independent of the size, ionization status, shape and other physical characteristics of the liquid solutions it measures.

Parts and supplies

Part number	Product description
Instrument	
OsmoTECH	Single-Sample Micro-Osmometer
Calibration standards, reference solutions and testing supplies	
SK-OsmoTECH	**Convenience Kit includes:** • Micro-Sample Test Kit; 1 box each of 250 chamber cleaners and 250 sampler tips, 1 plunger wire (TECH250) • Calibration Standard; 50 mOsm to 2mL Ampule, Pkg 10 (3MA005) • Reference Solution; Clinitrol 290 to 2mL Ampule, Pkg 10 (3MA029) • Calibration Standard; 850 mOsm to 2mL Ampule, Pkg 10 (3MA085) • Calibration Standard; 2000 mOsm to 2mL Ampule, Pkg 10 (3MA200) • Osmolality Linearity Set; 5-Level, 5mL Ampule, Pkg 10 (3LA028)
3MA000	• Calibration Standard; 0 mOsm to 2mL Ampule, Pkg 10

1. Subject to change
2. Performance at Reference Conditions: 20 °C to 25 °C (68 °F to 77 °F); 40 to 60% relative humidity.
3. Operating Conditions: Temperature 18°C to 35°C (64°F to 95°F); 30 to 80% relative humidity (non-condensing)
4. Dimensions when Micro-Sample Test Kit is on the instrument

Specifications[1]

Sample type	Aqueous solution
Sample volume	20 ±1 µL
Test time	90 seconds
Sample capacity	Single sample
Resolution	1 mOsm/kg H_2O
Range	0 to 2000 mOsm/kg H_2O
Accuracy[2] **(AI standards and reference solutions)**	±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 2000 mOsm/kg H_2O (1 SD)
Within-Run Repeatability[2] **(AI standards and reference solutions)**	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 2000 mOsm/kg H_2O
Temperature effects[3]	< 1 mOsm/kg H_2O per 5°C (9°F) ambient temperature change
Supported languages	Simple Chinese, English, 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 (D x W x H)[4]	38 cm x 36 cm x 29 cm (15" x 14" x 11.5")
Net weight	6.0 kg (13.3 lbs.)
Shipping weight	11.4 kg (25 lbs.)
Warranty	One-year limited warranty on workmanship and parts

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

ADVANCED INSTRUMENTS
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aicompanies.com

Not for patient diagnostic use

Intertek 98214

Advanced Instruments certifies that the technical features needed for 21 CFR Part 11 and EU Annex 11 compliance are built into OsmoTECH. 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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Request a quote or demo: aicompanies.com/osmotech-quote