OSMOTECH

OsmoTECH™ Single-Sample Micro-Osmometer

Critical during development and manufacture of biological therapeutics and injectable solutions

Supports 21 CFR Part 11 compliance

Osmolality testing is a robust in-process control and quality check you can implement throughout process development to ensure optimum media preparation, cell health, and product quality and yield.

OsmoTECH's data management features **support 21 CFR Part 11 compliance**, and its gold-standard testing method uses freezing point depression to provide the accuracy and precision you need to optimize your process and quality control program.

ADVANCED INSTRUMENTS

Why test osmolality?

During development of biological drugs or therapeutic molecules, it's important to test osmolality throughout the 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 critical therapeutics to patients. **— If you're not routinely testing osmolality, you're putting your biological drug at risk.**

Why OsmoTECH?

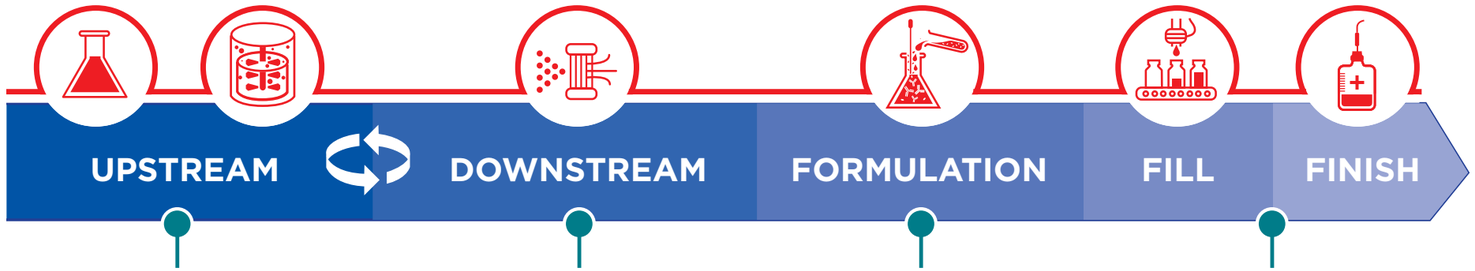
OsmoTECH is an easy-to-use, reliable system that provides a critical quality measure you can easily fit into your workflow.

With OsmoTECH, you can:

- Optimize cell health and improve product yield
- Manage data and security with features that support 21 CFR Part 11 compliance
- Ensure accurate media and buffer preparation
- Identify process issues and avoid expensive batch loss
- Avoid product stability issues and patient discomfort

Optimize your bioproduction process

You need robust process development—where you can create reproducible processes at each stage—so you can have confidence 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.



Critical lot release test for media production to guarantee quality and consistency. As you scale, it's critical to monitor cell culture and fermentation to ensure optimal cell health to optimize drug product quality and yield.

Critical in-process and lot-release test for raw materials and process reagents. Ensures accurate buffer preparation as purification begins, and proves complete buffer exchange to minimize expensive batch failures and lengthy quality investigations.

Confirm stability and safety of biologic during storage, reconstitution, and injection.

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

Your biotech production needs precision—OsmoTECH delivers

The bioproduction process is demanding. Timing is critical, and there are many inherent risk factors, such as human error, that impact your biological product development process. Each phase in the development process is critical and you need confidence that your therapeutic meets specification.

By the time your biological drug is ready for production release, you've invested time and money. You need confidence that your quality control is robust and your development process is reliable.

Why freezing point depression?

Freezing point depression is the gold standard osmolality testing method and the preferred standard throughout the world.

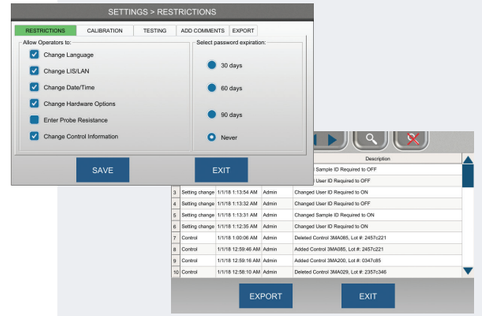
- Measurements are fast and accurate
- Easy-to-use and reliable
- Works well with small sample sizes
- Works with almost any liquid matrix
- Provides a full characterization of concentration

Other methods, including: specific gravity, refractive index, and conductivity, do not provide a complete view of a sample. **Only freezing point osmolality is truly independent from the size, ionization status, shape, and other physical characteristics of the liquid solutions.**

Features and benefits

Features that support 21 CFR Part 11 compliance

- **Password-protection**: Ensures security and traceability
- **Audit trail**: Time stamped records can't be modified
- **Fraud detection**: Completed test records can't be modified
- **Access controls**: Administrators can set up user accounts
- **Electronic signatures**: User passwords encrypted for data storage



Manage and transfer data efficiently

- **Storage**: 1,000 test results and 10,000 events
- **2D barcode scanner**: Eliminate transcription errors
- **Download data**: Supports .csv and .pdf formats; or disable
- **Secure LIS link**: Integrates with Laboratory Information System (LIS) using TCP/IP
- **Embedded web server**: Remotely view, print, and download results from a network browser
- **Network time synchronization**: Ensure accurate time stamp/record alignment
- **Dot matrix printer (optional)**: Prevents records from fading

Easy-to-use, flexible system

- **Fast**: 90-second test time
- **One-step direct sampling**: Simply aspirate sample and load
- **Touchscreen**: Color-coded, easy-to-use and intuitive
- **Onscreen messaging**: Instructional, status and statistics (mean, standard deviation, coefficient of variation)
- **Clean room compatibility**: Plastic corrugate consumable box
- **Prevents sample transfer loss**: Perfect for testing slightly viscous samples

Learn more: aicompanies.com/OsmoTECH

Request a quote today: aicompanies.com/OsmoTECH-quote

Parts and supplies

Part number	Product description
Instrument	
OsmoTECH	Single-Sample Micro-Osmometer
Reference Solutions	
3MA005	50 mOsm/kg calibration standard, 10x2 mL
3MA085	850 mOsm/kg calibration standard, 10x2 mL
3MA200	2000 mOsm/kg calibration standard, 10x2 mL
3MA029	Clinitrol™ 290 reference solution, 10x2 mL
3LA028	Osmolality linearity set, 5x2x5 mL
3LA011	100 mOsm calibration standard, 10x5 mL
3MA020	200 mOsm calibration standard, 10x2 mL
3MA040	400 mOsm calibration standard, 10x2 mL
3LA051	500 mOsm calibration standard, 10x5 mL
3LA091	900 mOsm calibration standard, 10x5 mL
3MA100	1000 mOsm calibration standard, 10x2 mL
3LA151	1500 mOsm calibration standard, 10x5 mL
Osmometer supplies and accessories	
TECH500	Micro-Sample Test Kit: 2 boxes of 250 tips and cleaners; 1 plunger wire
3M0825	20 µL Ease-Eject™ Sampler
135022	Printer, dot matrix

Specifications[1]

Sample type	Aqueous solution
Sample volume	20 ± 1 µL
Test time	90 seconds
Sample capacity	Single sample
Units	mOsm/kg H_2O
Resolution	1 mOsm/kg H_2O
Range	0 to 2000 mOsm/kg H_2O
Accuracy[2]	0 to 400 mOsm/kg H_2O: ≤ 2 mOsm/kg H_2O from nominal value (1 SD) > 400 to < 1500 mOsm/kg H_2O: ≤ 0.5% from nominal value (1 SD) ≥ 1500 to 2000 mOsm/kg H2O: ≤ 1% from nominal value (1 SD)
Precision[2] (within run repeatability)	0 to 400 mOsm/kg H_2O: Standard deviation ≤ 2 mOsm/kg H_2O > 400 to < 1500 mOsm/kg H_2O: Coefficient of variation ≤ 0.5% mOsm/kg H_2O ≥ 1500 to 2000 mOsm/kg H_2O: coefficient of variation ≤ 1% 0.5% mOsm/kg H_2O
Temperature effects[3]	< 1 mOsm/kg H_2O per 5°C (9°F) ambient temperature change
Communications	USB 2.0 Type A ports (2), USB 2.0 Type B ports (1), Ethernet 10/100, RJ45 connector port (1), dot matrix printer (optional)
Supported languages	Simplified Chinese, Czech, Danish, English, French, German, Greek, Italian, Japanese, Korean, Portuguese, Russian, Slovak, Spanish, Swedish, 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

1. Subject to change
2. Accuracy and precision (within run) specifications apply to Advanced Instruments standards and reference solutions. 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

Not for patient diagnostic use

Intertek 98214

RoHS

ADVANCED INSTRUMENTS

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PCN00488 MP00042, Rev.0