

## Osmometer for Measurement of Osmolality in Pharmaceuticals



### **Application**

Osmolality measurements using an osmometer are regularly carried out in the pharmaceutical industry and research labs to establish the isotonicity of intravenous solutions, injections, protein preparations, rehydration formulations and nasal & eye drops. Preparations which are hypertonic or hypotonic can cause severe irritation when introduced into the bloodstream or tissue or when applied to mucous membranes like cornea and wounds.

These pharma preparations are developed to closely match the osmolality of blood or body fluids to reduce the irritation caused by them. Hence accurately measuring osmolality is critical in manufacturing these pharma products.

Also, changes in osmolality of a preparation can be used as guide to the breakdown of a substance in solution and is therefore used in stability testing.

### **Pharmacopoeia Requirement**

Osmolality measurement using osmometer is a pharmacopeia requirement for numerous products. Few international Pharmacopoeias (US, Russia) gives the option of using either vapor pressure based osmometer or a freezing / cryoscopic point based osmometer for the measurement of osmolality. Whereas other Pharmacopoeias only describes the cryoscopic osmometer for the measurement of osmolality since these are more widely available.

### **Why vapor pressure osmometer ?**

For effective use in Pharma industry, the Vapro® Osmometer offers following unique advantages:

- *Vapor Pressure method*

Thermodynamic limitations of vapor pressure osmometry are least restrictive for a sample type.

The vapor pressure method determines osmolality at room temperature with the sample in natural equilibrium. This precludes cryoscopic aberrations due to high viscosity, suspended particles, protein content or other conditions that can interfere with freezing point determinations, giving Vapro® a much broader range of error-free applications.

For these reasons, vapor pressure osmometry is the method of choice for most fluids in biology and medicine in which water is the prime solvent

- *Superb Accuracy*  
Unsurpassed by any other method, error is less than 1% in the clinical range.
- *Easy & Automated calibration*  
A push of a button automatically sets the calibration parameters.
- *Short measurement time of 90 seconds*
- *Low sample volume of only 10 µl*  
Ideal for expensive or hard to obtain samples, allowing multiple measurements from small sample volume.
- *Three-point calibration*  
Giving high accuracy as mandated by regulatory guidelines.
- *Self-cleaning process*  
Self-cleaning thermocouple reduces user-level maintenance and improves performance.
- *Comes with Vapro Lab Report software*  
For easy transfer of Calibration data, QC data and sample results to a linked PC for records and traceability.

The system is being used in many renowned manufacturing units across the world, complying to stringent regulatory norms and accreditation guidelines.

Bibliography for further reading:

- Osmolality Measurements for High-Concentration Protein–Polymer Solutions : Variation Based on Working Principles of Osmometers [BioProcess International June 2016]  
*Erinc Sahin, Aastha Puri, Vishal Nashine, Mehrnaz Khosravi, and Rajesh Gandhi : Bristol-Myers Squibb, New Brunswick, NJ 08903, USA*
- Limitations of methods of osmometry: measuring the osmolality of biologicals [American Journal of Physiology-Regulatory]  
*T. E. Sweeney, and C. A. Beuchat : Dept. of Biology, Univ. of Scranton, Pennsylvania & Dept. of Biology, San Diego State Univ. CA, USA*
- Randomized, masked, in vitro comparison of three commercially available tear film osmometers : [Clinical Ophthalmology Jan 2017]  
Guillermo Rocha, Eric Gulliver, Armand Borovik, Clara C Chan : *Department of Ophthalmology, University of Manitoba, Winnipeg and Department of Ophthalmology and Vision Sciences, University of Toronto, Canada*
- US Pharmacopeia [(785) Osmolality and Osmolarity]