

# Osmolality Standards



## Summary of Features & Benefits:

### Commercial Benefits

- Extended shelf life
- Can be used with any brand of Osmometer
- Extensive range 50 - 3000mOsm/kg H<sub>2</sub>O (including protein based and urine based standards)
- Presented in convenient ampoules
- Ready to Use


### Technical Benefits

- ISO/IEC 17025 accredited for range 50 - 3000mOsm/kg H<sub>2</sub>O (INAB Ref:264T)
- Low Uncertainty of Measurement
- Manufactured in accordance with European and United States Pharmacopoeia guidelines where appropriate
- Consistency of product - Independent, Traceable, Certified
- Certificates of Analysis and Safety Data Sheets available online


Reagecon manufactures a range of Osmolality Standards for ease of use when calibrating all types of Osmometers, irrespective of brand. All Osmolality standards are manufactured using high purity raw materials in accordance with European and United States Pharmacopoeia guidelines where appropriate. These products are prepared gravimetrically and are on a weight/weight basis. Both solute (salts) and solvent (water) are weighed on a balance calibrated by Reagecon engineers using OIML traceable weights. Reagecon holds ISO 17025 accreditation for calibration of laboratory balances (INAB Ref:265C). The resulting Balance Certificate of Calibration is issued in accordance with the requirements of ISO/IEC 17025. The Osmolality of the standard is verified using a high performance calibrated, temperature controlled Osmometer. The calibration of this instrument is completed using high purity certified Osmolality standards similar in value to the products listed below.

Product No.	Description	European Pharmacopoeia 2.2.35 United States Pharmacopoeia <785>	Pack Size
RE-OSM-50	50mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-100	100mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-200	200mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-290	290mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-300	300mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-400	400mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-500	500mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-600	600mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-700	700mOsm/Kg H <sub>2</sub> O	conforms	12 x 5ml
RE-OSM-850	850mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-OSM-900	900mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-OSM-1000	1000mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml

Product No.	Description	European Pharmacopoeia 2.2.35 United States Pharmacopoeia <785>	Pack Size
RE-OSM-1500	1500mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-OSM-2000	2000mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-OSM-2500	2500mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-OSM-3000	3000mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-POSM-240	Protein Based 240mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-POSM-280	Protein Based 280mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-POSM-320	Protein Based 320mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-ROSM-300	Urine Based 300mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml
RE-ROSM-800	Urine Based 800mOsm/Kg H <sub>2</sub> O	Not Applicable	12 x 5ml



ISO 17025  
IVNAB  
ACCREDITED  
TESTING  
DETAILED IN SCOPE REG.NR.264T



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**CERTIFICATE OF ANALYSIS**

**PRODUCT:** 900mOsm/Kg H<sub>2</sub>O Osmolality Standard

**PRODUCT NO:** RE-OSM-900

**LOT NO:** OSM90015B1

**DATE OF TEST:** 6<sup>th</sup> February 2015

**EXPIRY DATE:** 28<sup>th</sup> February 2018

**SPECIFICATION:** 891 – 909mOsm/Kg H<sub>2</sub>O

**MEAN:** 897 mOsm/Kg H<sub>2</sub>O

**TEST METHOD:**

The result reported above was determined by analysis of a sample of this lot taken at time of manufacture. The value of the standard was determined using a high performance calibrated, Osmometer according to TPOSM-1500.

This certificate relates solely to the lot number given above.

The uncertainty of measurement as been calculated not to exceed ± 1.2% Osmolality value at 95% confidence level, i.e. coverage factor k=2.

**ACCREDITATION:**

Reagecon Diagnostics Ltd. is accredited by the Irish National Accreditation Board, under scope 264T, for the test method, TPOSM-1500, used to generate the above result. This accreditation is intended only to certify that Reagecon has the Quality Management Systems in place to ensure that each individual test result generated using TPOSM-1500 is technically valid and is supported by appropriate uncertainty measurements.

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**TRACEABILITY IN THE PRODUCTION OF THIS STANDARD:**

This product was prepared gravimetrically on a weight/weight basis. Both solute and solvent were weighed on a balance calibrated by Reagecon engineers using OIML traceable weights. Reagecon holds ISO 17025 accreditation for calibration of non-automatic weighing machines (265C). The resulting Balance Certificate of Calibration was issued in accordance with the requirements of ISO/IEC 17025. The balance was calibrated under monitored environmental conditions and atmospheric pressure. Tests were performed for capacity, readability, repeatability, eccentricity and linearity.

**BALANCE ID No.:** RDP-190

**CALIBRATION DATE OF BALANCE:** 20<sup>th</sup> December 2014

**CALIBRATION AUTHORITY OF BALANCE:** Reagecon Diagnostics Ltd, ISO17025 Accreditation No. 265C

**WEIGHTS No.:** RDP-191

**CALIBRATION DATE OF WEIGHTS:** 20<sup>th</sup> December 2014

**CALIBRATION AUTHORITY OF BALANCE:** Reagecon Diagnostics Ltd, ISO17025 Accreditation No. 265C

**Approved By:** Quality Manager

*Darren Mc Jannet*

**Date:** 6<sup>th</sup> February 2015

This certificate must not be reproduced except in full.

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