

Certificate of Analysis

Osmolality Standard 100 mOsm/Kg (Prepared and tested according to USP Monograph methods).

Product code:	BS12519.
Description:	Osmolality Standard 100 mOsm/Kg (Prepared and tested according to USP Monograph methods).
Chemical Name:	NA.
Pack Size:	5 ml x 10 No's.
CAS NO.:	NA.
Mol. Weight:	NA.
Mol. Formula:	NA.
Solubility:	Miscible in water.
Accuracy:	±2%.
Storage:	Store at ambient temperature.
Batch No:	BS12519/11.
Manufacture Date:	05/08/2026.
Expiry Date:	04/08/2029.

Characteristics	Specification	Result
Appearance:	Colourless clear Liquid.	Colourless clear Liquid.
Odour:	Odourless.	Odourless.
Osmolality:	98 - 102 mOsm/Kg.	99 mOsm/Kg.

Please Note: - This material is only for laboratory purpose and not for human consumption.

Certification & Traceability:

This product was manufactured, processed and/or certified under a quality management system that complies with **ISO 17034:2016**. This product was analysed according to protocol mentioned in **USP**. The present lot specifications comply with the corresponding **USP** lot specifications.

All standard components used in the manufacture of this product are pre-qualified and verified before use. All glassware used are of class A and have been qualified and verified before use. Tests were performed for capacity, readability, repeatability and linearity. This product meets all requirements defined by the appropriate specifications. This product is manufactured, packaged, stored, and shipped in accordance with good manufacturing practices.

The balances used in the preparation of this product are calibrated regularly, using a calibration provider that is accredited to **ISO/IEC 17025**. All standard components used in the manufacture of this product are pre-qualified and verified before use.

Tests were performed for capacity, readability, repeatability and linearity. This product is manufactured, packaged, stored, and shipped in accordance with good manufacturing practices that is certified to **WHO-GMP**. The uncertainty associated with each certified concentration represents the expanded uncertainty at the 95% confidence level using a coverage factor of **k=2**.

Validity Period:

Briti Scientific standards ensure the accuracy of this product for 3 years from the manufacture date given above, provided the instructions for use are followed.

Quality Certifications:

This product was prepared under a quality management system that complies with the following:
17034:2016: Reference Materials Producer, CGI Certificate No. UG/25540 – General Requirements for the Competence of Reference Material Producers.

ISO 17034 references additional requirements specified in ISO Guide 31 and ISO Guide 35.

ISO/IEC 17025:2017 Accredited: Testing, NABL Certificate No. NABLT0726TS18722 - General Requirements for the Competence of Testing and Calibration Laboratories.

ISO 9001:2015 Certified: Quality Management Systems, CGI Certificate No. QMS/26343.

WHO-GMP Certified: Good Manufacturing Practices, CGI Certificate No. WGMP/25541.

Homogeneity:

This product was determined to be homogenous by procedures consistent with the requirements of **ISO 17034** and **ISO Guide 35**. Replicate samples of the finished solution were analysed to confirm its homogeneity, in accordance with internal procedures for the assessment of homogeneity and stability.

Health and Safety Information:

Refer to the Safety Data Sheet (SDS), which can be obtained at www.britishtscientific.com.

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Dr. K. Viswanath.

Director - Technical.