Characterization methods are Accredited according to ISO 17034:2016

PRODUCT INFORMATION SHEET

Sodium Chloride

IUPAC Name: Sodium Chloride
CAS No: 7647-14-5

Structure:

Identification:

Version No.: 02	**Certificate No:** DRA/RM/S-01/25/005
Lot No.: 005	**Catalogue Number**:S-01
Unit Quantity: 45 gm	**Chemical Formula**: NaCl
Molecular Weight: 58.44 g/mol	**Assay**: 99.50 per cent
Date of issue : 18/08/2025	u_{CRM}= ± 0.15
Manufacturing: August 2025	**Valid up to :** July 2028
Storage: Keep container tightly closed, protected from light and store between 2°C to 8°C.	

Uncertainty

The assigned Uncertainty covers uncertainty contribution from Characterization, In homogeneity, Storage & transport stability etc (wherever applicable) , is the combined standard Uncertainty ,calculated using a coverage factor (K= 2) which gives a level of confidence of approx.95%. As per ISO 17034:2016 & ISO Guide 35, for this pharmaceutical standard assigned uncertainty value is considered to be negligible w.r.t. defined limits of method specific assays for which the DRA/CRM is used.

Metrological Traceability and Measurement methods

Assigned value is traceable to SI units through use of Primary Standard mass balance methods (Physical & Chemical) with Inter Laboratory Collaborative studies using Indian Pharmacopeia standards specifications. Characterization done by combination of Primary Reference Methods viz. ICP-MS, ICP-OES, with use of pure substance/traceable RM/CRM in compliances with ISO Guide 35 & ISO/IEC-17025.

Commutability

Not Applicable

Intended Use

This reference material is intended for use as a primary standard.

Instruction for handling and use

Allow the sealed container to equilibrate at ambient/room temperature before opening for use. Do not dry, use "As on basis".

Validity

Stated Validity is applied, when material stored under recommended conditions with proper handling.

Associated uncertainty:

The associated uncertainty U_{CRM} reported with the certified values is calculated as combined expanded uncertainty UCRM=k.U_{CRM} in accordance with EA 4/02 with k=2 as the coverage factor for a 95 % coverage probability.

The combined uncertainty Ucrm is derived for combination of the squared uncertainty contribution:

$$U_{CRM} = \sqrt{U^2_{Charaterisation} + U^2_{Homogeneity} + U^2_{Stability}}$$

$U_{Charaterisation}$: Is the uncertainty in accordance with ISO/IEC 17025 which includes the contribution of the primary reference material and the measuring system.

$U_{Homogeneity}$: Is the between bottle variance in accordance with ISO 17034. The assessment of homogeneity is performed by analysis of a representative number of systematically chosen samples units.

$U_{Stability}$: Is the uncertainty obtained from short term and long term stability in accordance with ISO 17034. The Stability studies are the basis for the quantification of the expiry date of this volumetric standard for the unopened bottle.

ICP-MS, ICP-OES:

The Material confirms to ICP-MS, ICP-OES.

Accreditation:

The laboratory of Dove Research& Analytics Unit-II (RMP Division), is Accredited as per ISO 17034:2016; General requirements for the competence of reference material producers and ISO/IEC 17025 General requirement for the competence of testing and Calibration Laboratories.

Safety Information

Refer to the material safety data sheet.

Special Note

DRA reference materials are designed and intended to be used in the forms in which they are sold. All values (Certified, non-certified, reference or information) are nullified if the RM is stored or used improperly, damaged, contaminated or otherwise modified in any manner.

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Approving Officer

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