

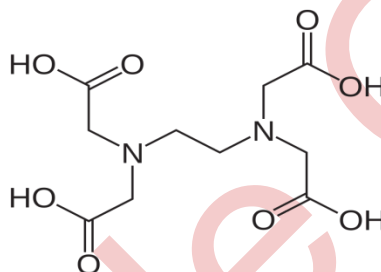
Characterization methods are Accredited according to **ISO 17034:2016**

PRODUCT INFORMATION SHEET OF REFERENCE MATERIAL

DI SODIUM EDETATE

IUPAC Name: disodium dihydrogen ethylenediaminetetraacetate
CAS No: 6381-92-6

Structure:



Identification:

Version No.: 00	Certificate No: SRD/RM/D-02/25/001
Lot No.: RM/D/002/1	Catalogue Number: D-02
Unit Quantity: 5gm	Chemical Formula: $C_{10}H_{14}N_2Na_2O_8$
Molecular Weight: 336.21 g/mol	Assigned value : 99.46 percent
Date of issue : 22/12/2025	$u_{CRM} = \pm 0.52$
Manufacturing: Dec 2025	Valid up to : Nov 2027
Storage: Keep container tightly closed, protected from light, freezing , excessive heat and store between 2°C to 8°C.	

Description

White Crystalline Powder

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, ISO

33405:2024, for this pharmaceutical standard assigned uncertainty value is considered to be negligible w.r.t. defined limits of method specific assays for which the SRD/CRM is used.

Metrological Traceability and Measurement methods

Assigned value is traceable to SI units through use of 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. ¹H-NMR, Mass by LCMS, with use of pure substance/traceable RM/CRM in compliances with ISO Guide 35, ISO 33405:2024 & ISO/IEC-17025:2017.

Commutability

Not Applicable

Intended Use

This reference material is intended for use in pharmaceutical testing, validation or quality control of analytical method. This material cannot be use as “drug” or household.

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 $U_{CRM}=k.U_{CRM}$ in accordance with EA 4/02 with $k=2$ as the coverage factor for a 95 % coverage probability.

The combined uncertainty U_{CRM} is derived for combination of the squared uncertainty contribution:

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

$U_{Charaterisation}$: 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.

1H-NMR, Mass (By LCMS):

The Material confirms to 1H-NMR, MASS (By LCMS).

Accreditation:

The laboratory of Sabiha Research and Development LLP (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.

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Approving Officer

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