



R-0003

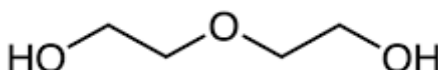
Characterization methods are Accredited according to **ISO 17034:2016**

PRODUCT INFORMATION SHEET OF REFERENCE MATERIAL

DIETHYLENE GLYCOL

IUPAC Name: 2,2'-Oxydiethanol
X CAS No:111-46-6

Structure:



Identification:

Version No.: 00	Certificate No: SRD/RM/D-03/25/001
Lot No.: RM/D/003/02	Catalogue Number: RM/D-03
Unit Quantity: 100mL	Chemical Formula: C ₄ H ₁₀ O ₃
Molecular Weight: 106.12 g/mol	Assigned value: 99.86percent
Date of issue: 20/07/2026	u_{CRM} = ± 0.23
Manufacturing: July 2026	Valid up to : June 2028
Storage: Keep container tightly closed, protected from light, freezing, excessive heat and store between 2°C to 8°C.	

Description

A clear, colourless liquid.

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



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33405, 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)) and to higher level of traceability (USP) 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 35,33405:2024 & ISO/IEC-17025.

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:

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

$U_{Charaterisation}$: 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.



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$U_{\text{Stability}}$: 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.

PURITY vs. USP REFERENCE STANDARD (1193265) (as is basis)

PURITY VALUE

99.86%

vs. USP

R147W0

Labeled Content = 1.00 mg/mg

METHOD: GC (ref.: Diethylene Glycol, Current Compendial monographs)

Column: DB-624, 30 m X 0.53 mm I.D., 3.0 μ m film thickness

Carrier Gas: N₂, Flow Rate 2.2 ml/min

Inlet Temperature: 250 °C, Injection Volume: 0.5 μ L

Injection Mode: Split ratio: 10:1

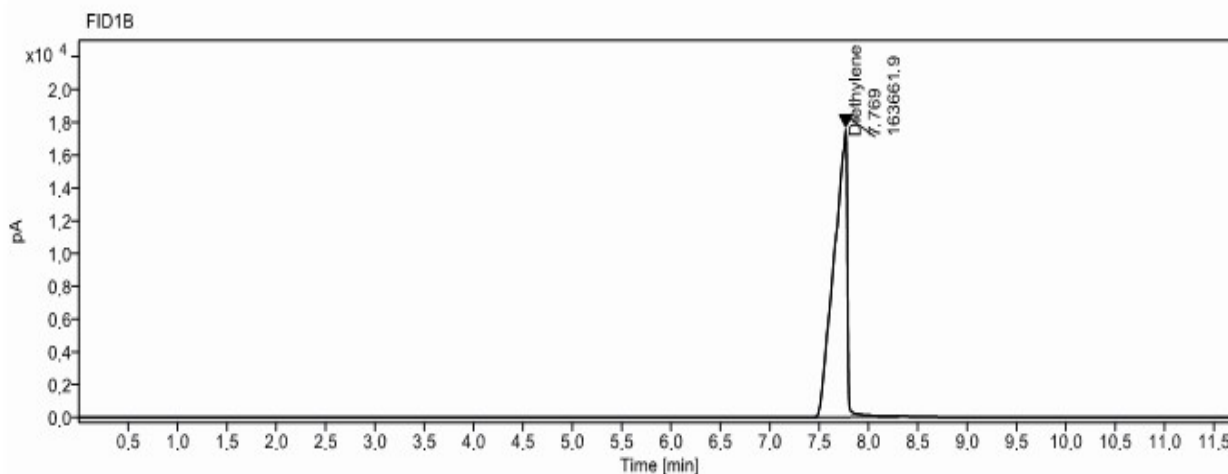
Temperature Program: 120 °C (Hold 1 min) @ 12 °C/min to 225 °C (Hold 2 min)

Detector: FID

Detector Temperature: 250°C

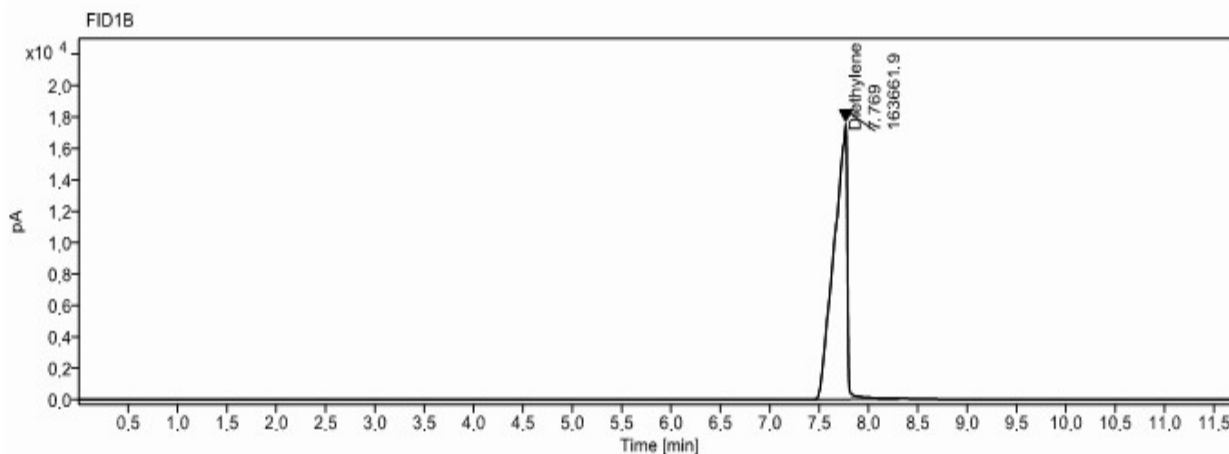
Certification Process Details: The Certified purity is determined by GC-FID by comparing with USP reference standard.

Representative Chromatogram from USP Reference Standard Lot No: R147W0



CERTIFIED PURITY BY GC-FID

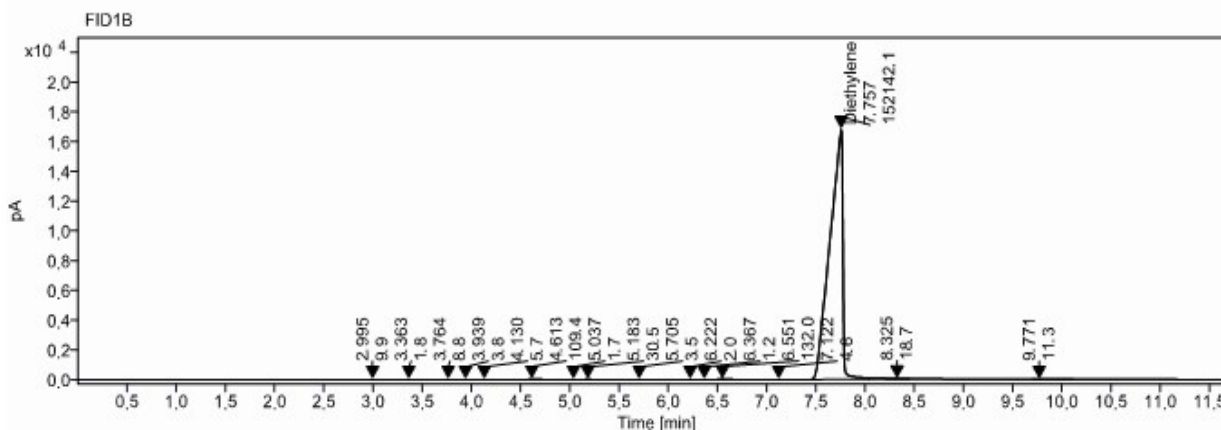
Representative Chromatogram from SRD Lot No.: RM/D/003/1



CHROMATOGRAPHIC IMPURITY ANALYSIS

METHOD: GC (ref.: Diethylene Glycol, Current Compendial monograph)

Representative Chromatogram from SRD Lot No: RM/D/003/1



See GC Purity:

Impurities Detected

Impurity 1:-0.006 % Impurity 2:-0.001 % Impurity3:-0.006 % Impurity4:-0.002 %

Impurity 5:-0.004 % Impurity 6:-0.072 % Impurity7:-0.021 % Impurity8:-0.028 %

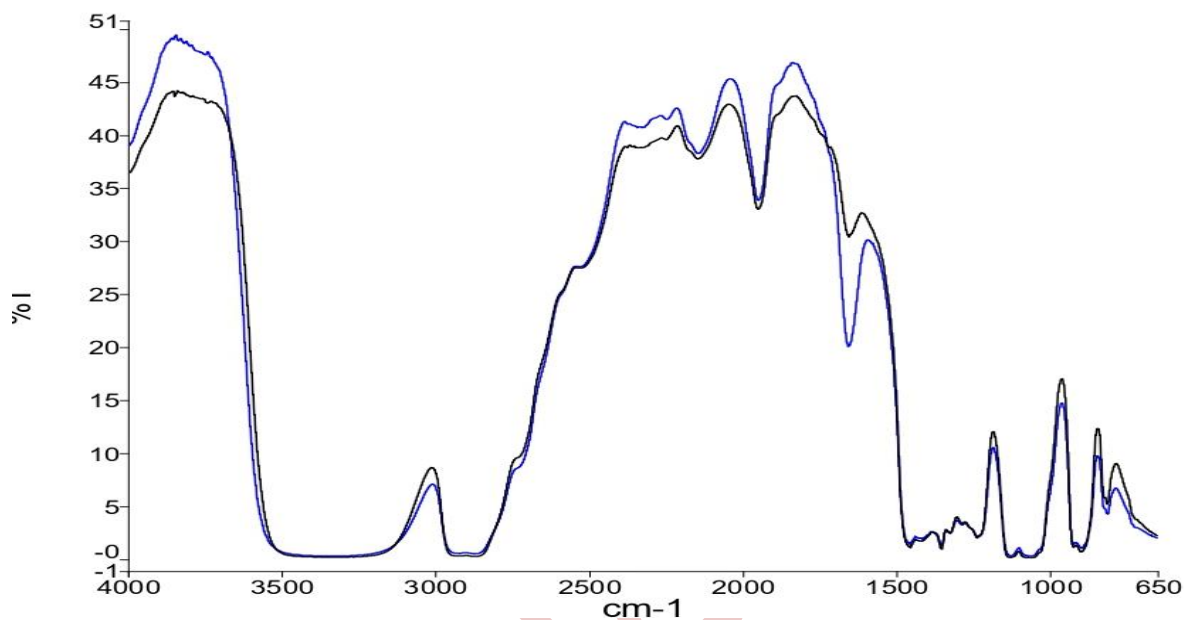
Total Impurities: 0.14 %



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IDENTIFICATION TEST: INFRARED SPECTROPHOTOMETRY

(Comparative identification analysis demonstrates direct traceability to Pharmacopeial standards)



USP Reference Standard Lot No: R147W0

SRD Lot No: RM/D/003/1

WATER DETERMINATION

Method: Karl Fischer (Ref.: Current Compendial Monographs)

Mean of three measurements, Water Content = 0.18 %

RESIDUE ANALYSIS

Method: Evaporation (ref.: Current Compendial Monographs)

Sample Size: 50 gm

Measurements, Residue = None

DENSITY

Anton Par DMA38 Density meter

Temperature: 25.0 °C

Mean of three measurements = 1.113 g/cm³

REFRACTIVE INDEX

Method: Refractive Index (ref.: Current Compendial Monographs)

Sample Size: 1.5gm

Measurements, RI =1.447



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1H-NMR, Mass (By LCMS):

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

Safety Information

Refer to the material safety data sheet.

Special Note

SRD Certified Reference Material (CRM)/ Reference Materials (RM) 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 Office

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