SRD

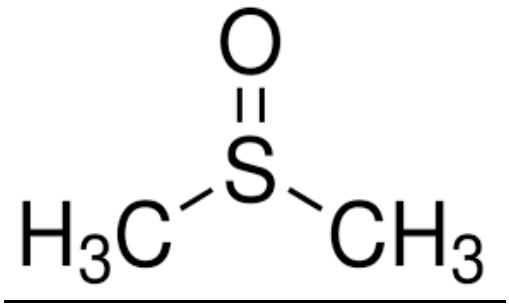
Characterization methods are Accredited according to **ISO 17034:2016**

PRODUCT INFORMATION SHEET OF REFERENCE MATERIAL

ETHYLACETATE

IUPAC Name: Ethyl ethanoate
CAS No: 141-78-6

Structure:



Identification:

Version No.: 00	**Certificate No:** SRD/RM/D-06/26/001
Lot No.: RM/E/003/1	**Catalogue Number**:E-03
Unit Quantity: 100 mL	**Chemical Formula**: $C_4H_8O_2$
Molecular Weight: 88.11 g/mol	**Assigned value** : 99.98 percent
Date of issue : 15/06/2026	$\mathbf{u_{CRM}}$ = ± 0.03
Manufacturing: June 2026	**Valid up to : May 2028**
Storage: Keep container tightly closed, store between 2°C to 30°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 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 and through use of Standard mass balance methods (Physical & Chemical) and higher level standards (USP) with Inter Laboratory Collaborative studies using Pharmacopeia standards specifications. Characterization done by combination of Primary Reference Methods viz. 1H-NMR, Mass by GCMS, 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 R&D and G. C reference standard only. This material cannot be used as “drug” or drug raw material.

Instruction for handling and use

Do not dry, use on the as is basis. The internal pressure of the container may be slightly different from atmospheric pressure at the user’s location. Open slowly and carefully to avoid dispersion of the material.

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.

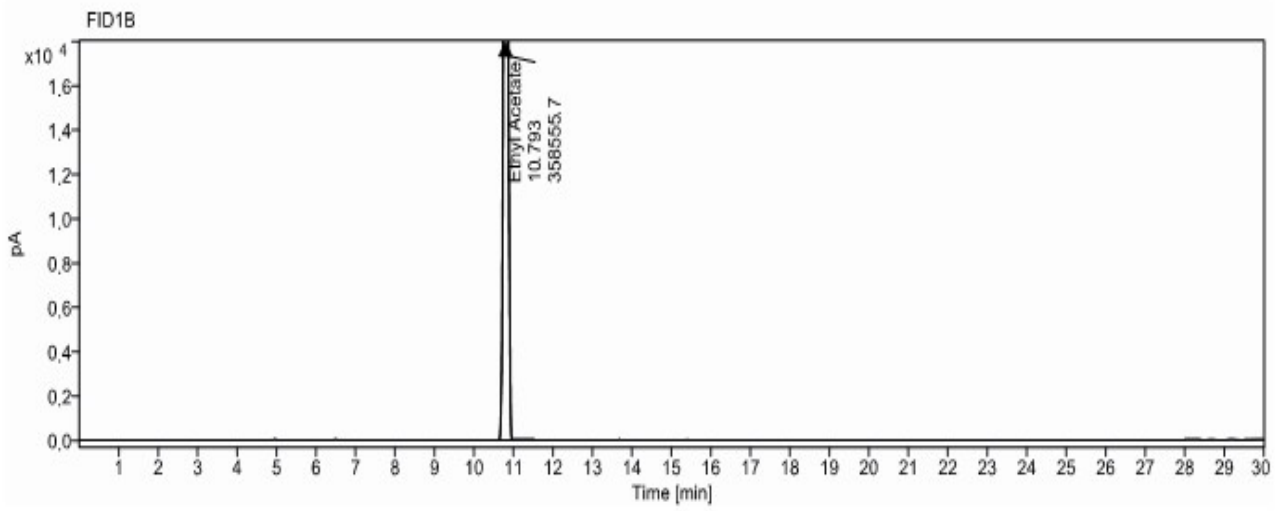
$U_{Homogeneity}$: Is the between bottle variance in accordance with ISO 17034. The assessment of homogeneity is performed by analysis of a representative number of systematically chosen samples units.

$U_{Stability}$: 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.

PURITY vs. USP Reference Standard (1265402) (as is basis)	
PURITY VALUE	***vs.USP***
99.98%	***R09350***
	Labeled Content = 1.00 mg/mg

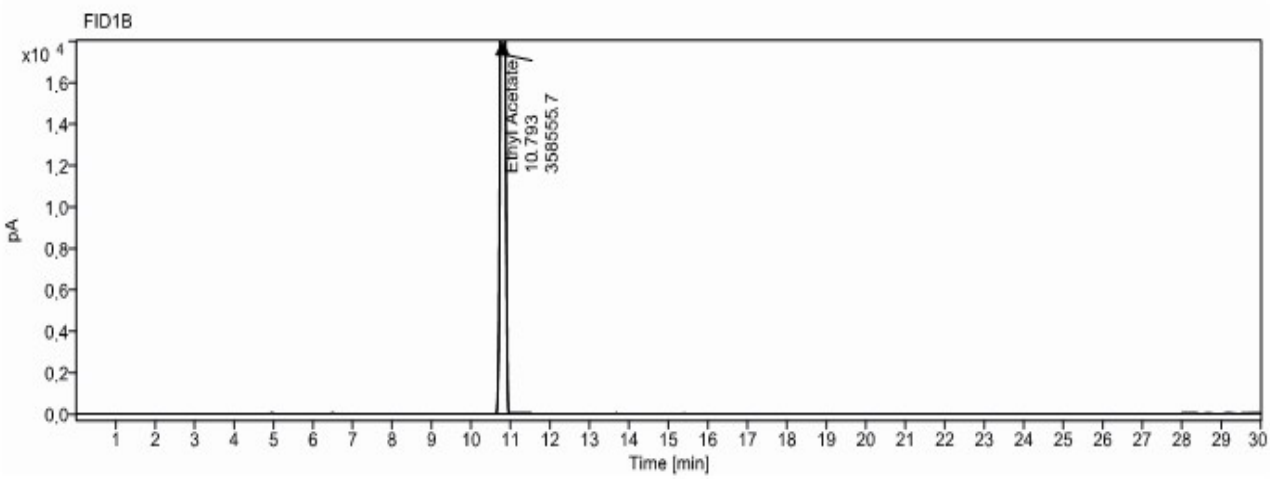
METHOD: GC (ref.: Ethyl Acetate, Current Compendial monographs)
Column: DB-624, 30 m X 0.53 mm I.D., 3.0 µm film thickness
Carrier Gas: N2 , Linearity Velocity:-20 cm/s
Inlet Temperature: 220 ◦C, Injection Volume: 1µL
Injection Mode: Split ratio: 20:1
Temperature Program: 40 ◦C (Hold 5 min) @ 10 ◦C/min to 240 ◦C (Hold 5 min)
Detector: FID
Detector Temperature: 280 ◦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: R09350



CERTIFIED PURITY BY GC-FID:

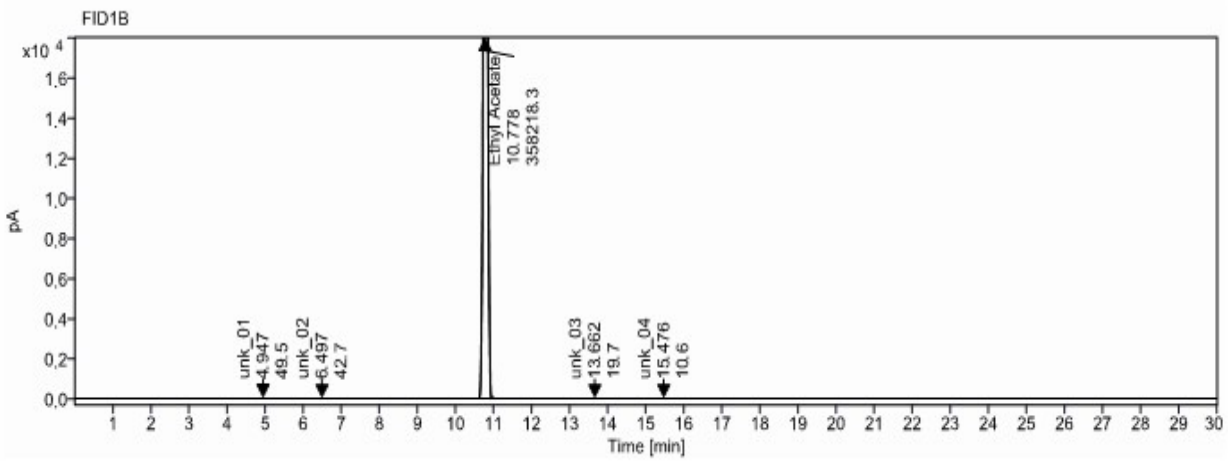
Representative Chromatogram from SRD Lot No: RM/E/003/1



CHROMATOGRAPHIC IMPURITY ANALYSIS:

METHOD: GC (ref.: Ethyl Acetate, Current Compendial monographs

Representative Chromatogram from SRD Lot No: **RM/E/003/1**



See GC Purity

Impurities Detected

Impurity 1: 0.005, Impurity 2: 0.005, Impurity 3: 0.006, Impurity 4: 0.004

Total Impurities: 0.02%

WATER BY KARL FISHER:

Method: Karl Fischer (Ref.: Current Compendial Monographs)
Mean of three measurements, Water Content = 0.03 %

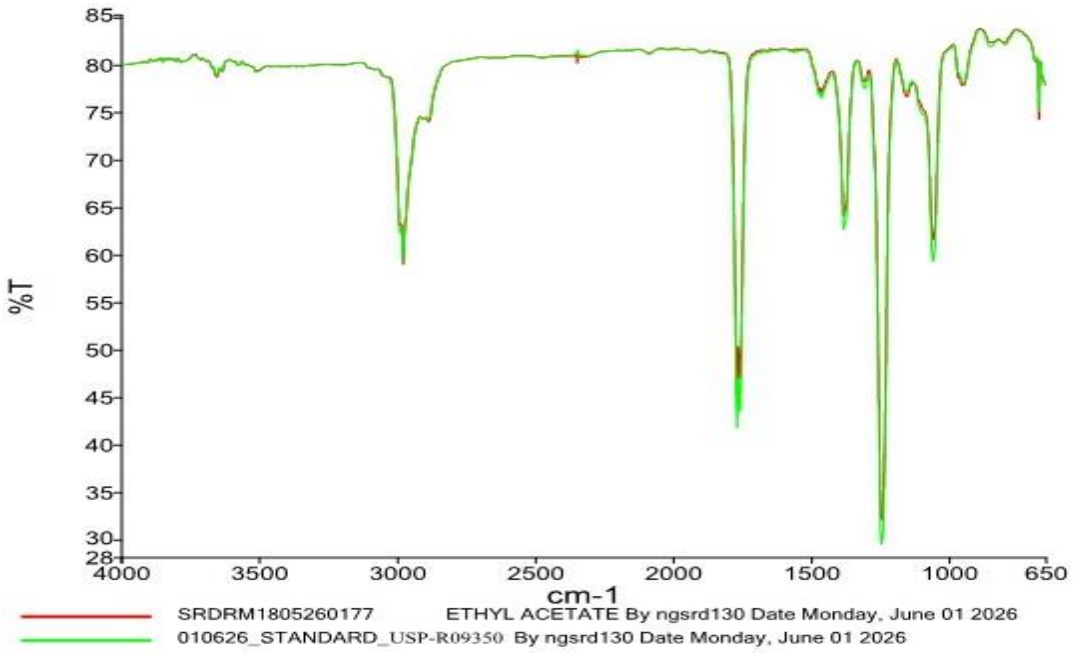
RESIDUE ANALYSIS:

Method: Evaporation (ref.: Current Compendial Monographs)
Sample Size: 50 gm or (50 x 0.902 = 45.1 mL)
Measurements, Residue = None

DENSITY:

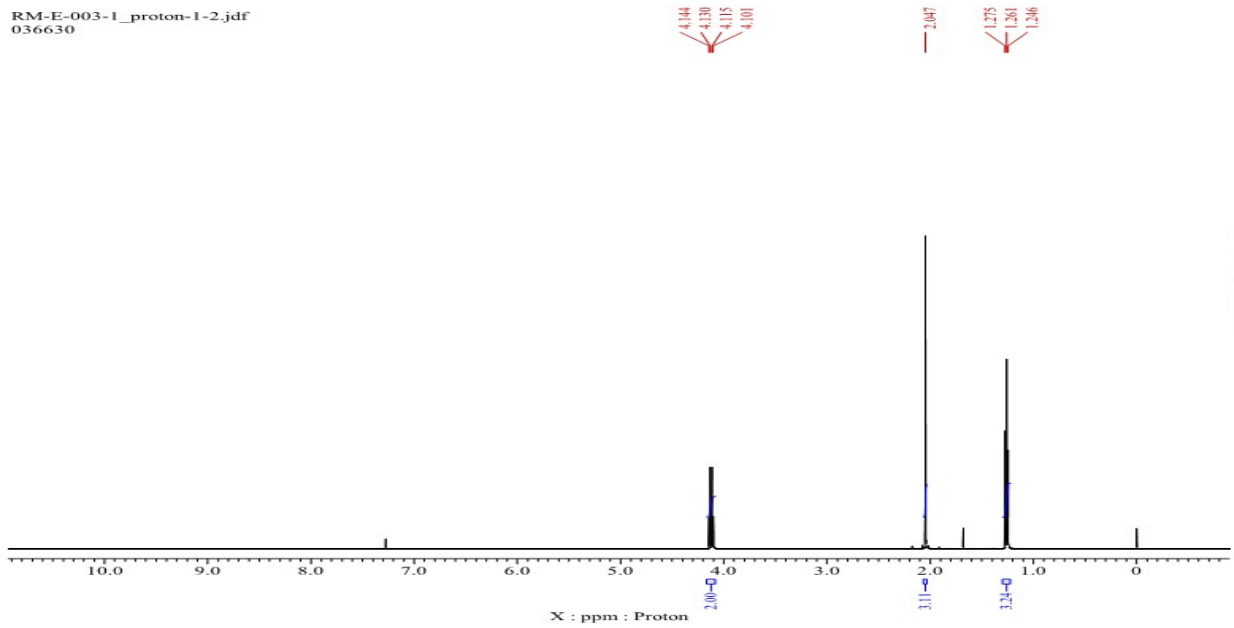
Anton Par DMA38 Density meter
Temperature: 25.0 ºC
Mean of three measurements =0.902 g/cm3

IDENTIFICATION TEST: INFRARED SPECTROPHOTOMETRY:
(Comparative identification analysis demonstrates direct traceability to Pharmacopeial standards)



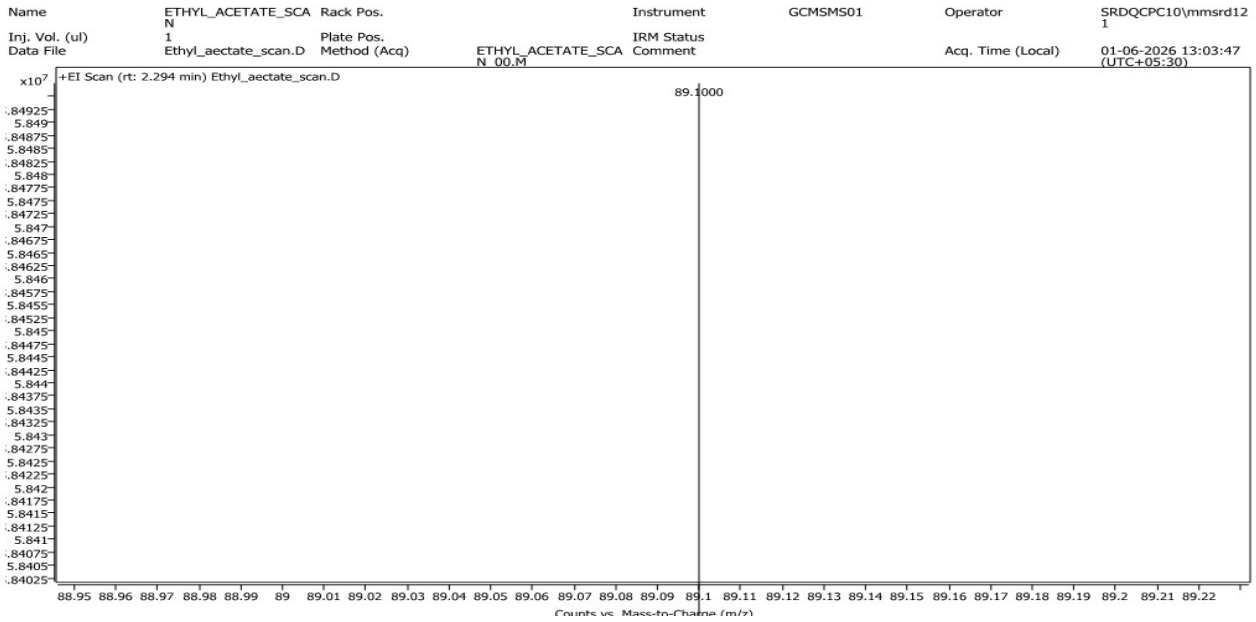
Sabiha Research and Development vs. USP Lot: **R09350 (1265402)**

1H-NMR:



The Material confirms to 1H-NMR

Mass (By GCMS):



The Material confirms to MASS (By GCMS).

Accreditation:

The laboratory of Sabiha Research and Development Ltd. (RMP Division), is Accredited as per ISO 17034:2016; General requirements for the competence of reference material producers and ISO/IEC 17025:2017 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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