



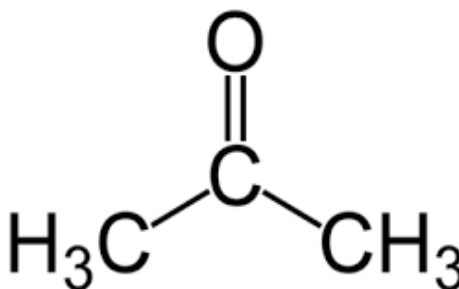
Characterization methods are Accredited according to **ISO 17034:2016**

## PRODUCT INFORMATION SHEET OF REFERENCE MATERIAL

### ACETONE

IUPAC Name: Propan-2-one  
CAS No: 67-64-1

#### Structure:



#### Identification:

|                                                                           |                                                          |
|---------------------------------------------------------------------------|----------------------------------------------------------|
| <b>Version No.:</b> 00                                                    | <b>Certificate No:</b> SRD/RM/A-02/26/001                |
| <b>Lot No.:</b> RM/A/002/1                                                | <b>Catalogue Number:</b> A-02                            |
| <b>Unit Quantity:</b> 100 mL                                              | <b>Chemical Formula:</b> C <sub>3</sub> H <sub>6</sub> O |
| <b>Molecular Weight:</b> 58.08 g/mol                                      | <b>Assigned value :</b> 99.98 percent                    |
| <b>Date of issue :</b> 15/06/2026                                         | <b>uCRM =</b> ± 0.04                                     |
| <b>Manufacturing:</b> June 2026                                           | <b>Valid up to :</b> May 2028                            |
| <b>Storage:</b> 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.  $^1\text{H-NMR}$ , 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 as 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 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  $U_{\text{CRM}}$  reported with the certified values is calculated as combined expanded uncertainty  $U_{\text{CRM}}=k.U_{\text{CRM}}$  in accordance with EA 4/02 with  $k=2$  as the coverage factor for a 95 % coverage probability.

The combined uncertainty  $U_{\text{crm}}$  is derived for combination of the squared uncertainty contribution:

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

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



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

$U_{\text{Stability}}$  : 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 (1006801) (as is basis)***

***PURITY VALUE***

***99.98%***

***vs. USP***

***R095B0***

***Labeled Content = 1.00 mg/mg***

METHOD: GC (ref.: Acetone, Current Compendial monographs)

Column: DB-624, 30 m X 0.53 mm I.D., 3.0  $\mu\text{m}$  film thickness

Carrier Gas: N<sub>2</sub> Linear Velocity: 35cm/sec

Inlet Temperature: 200 °C, Injection Volume: 1 $\mu\text{L}$

Injection Mode: Split ratio: 10:1

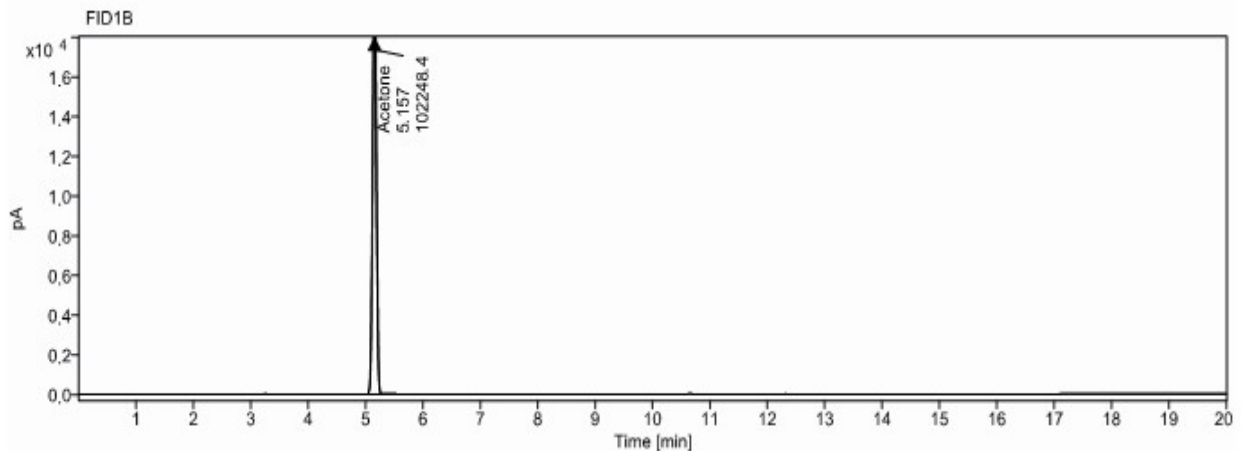
Temperature Program: 40 °C (Hold 5 min) @ 20 °C/min to 240 °C (Hold 5 min)

Detector: FID

Detector Temperature: 280 °C

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

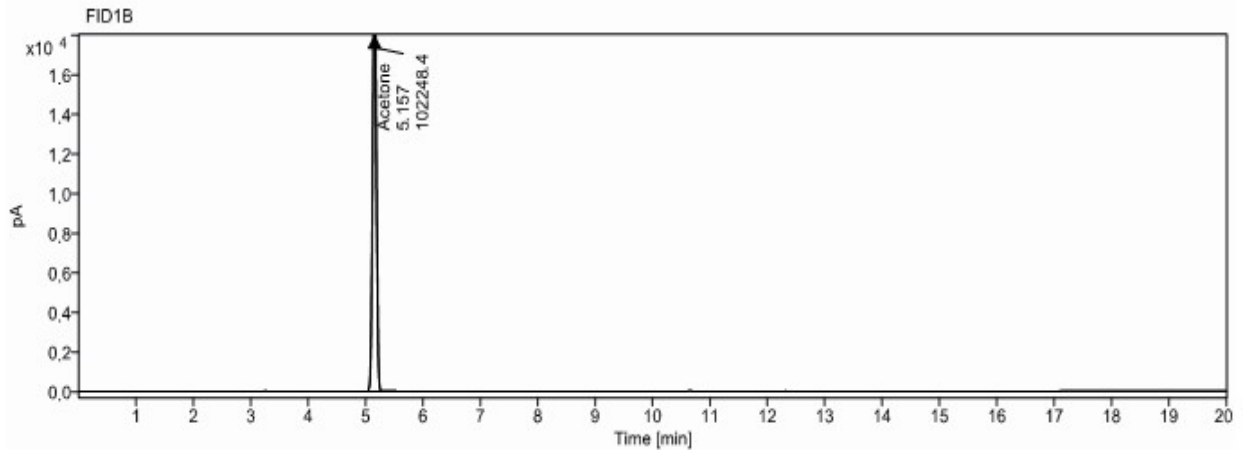
**Representative Chromatogram from USP Reference Standard Lot No: R095B0**





**CERTIFIED PURITY BY GC-FID:**

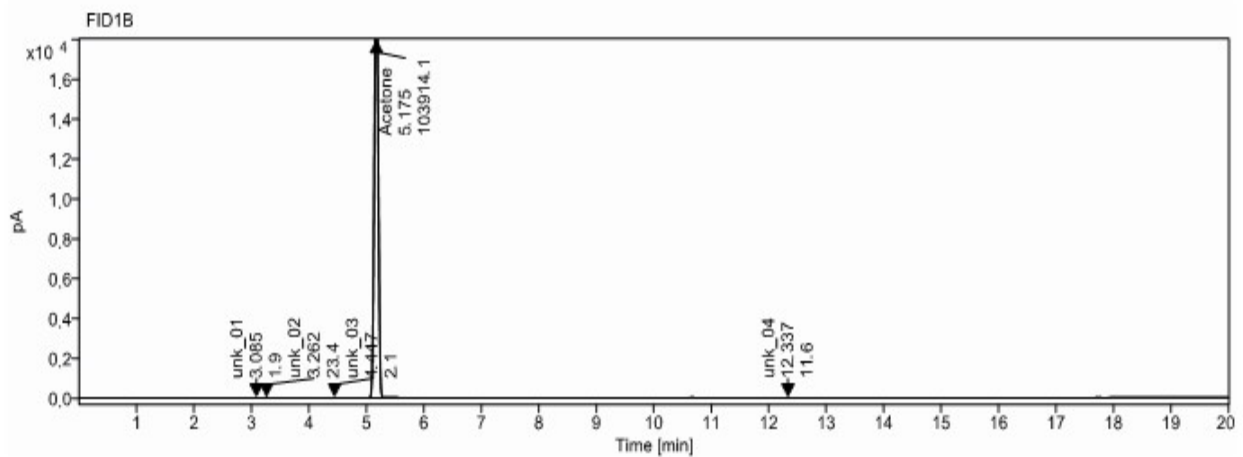
**Representative Chromatogram from SRD Lot No: RM/A/002/1**



**CHROMATOGRAPHIC IMPURITY ANALYSIS:**

METHOD: GC (ref.: Acetone, Current Compendial monographs)

**Representative Chromatogram from SRD Lot No: RM/A/002/1**



**See GC Purity**

Impurities Detected

Total Impurities: 0.02%



### **WATER BY KARL FISHER:**

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

Mean of three measurements, Water Content = 0.01 %

### **RESIDUE ANALYSIS:**

Method: Evaporation (ref.: Current Compendial Monographs)

Sample Size: 50 gm or (50 x 0.780 =39 mL)

Measurements, Residue = None

### **DENSITY:**

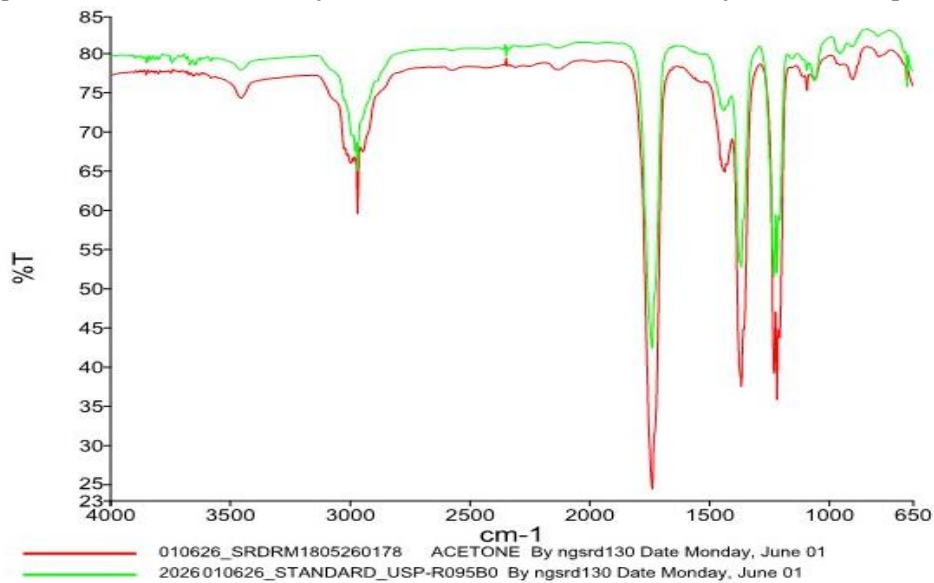
Anton Par DMA38 Density meter

Temperature: 25.0 °C

Mean of three measurements =0.780 g/cm<sup>3</sup>

### **IDENTIFICATION TEST: INFRARED SPECTROPHOTOMETRY:**

(Comparative identification analysis demonstrates direct traceability to Pharmacopeial standards)

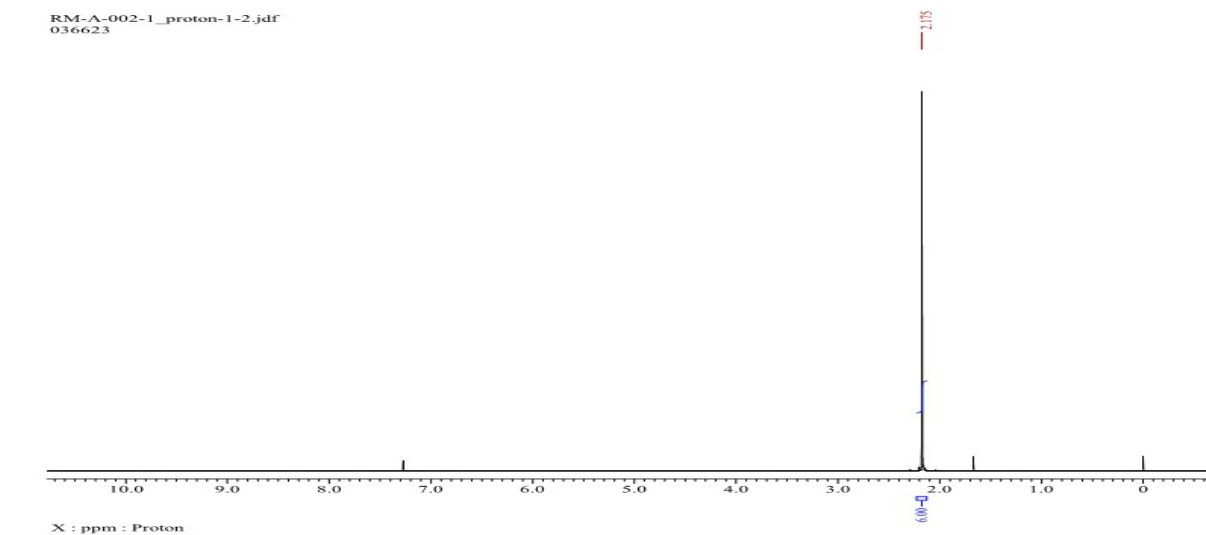


Sabiha Research and Development vs. USP Lot: **R095B0 (1006801)**



### 1H-NMR:

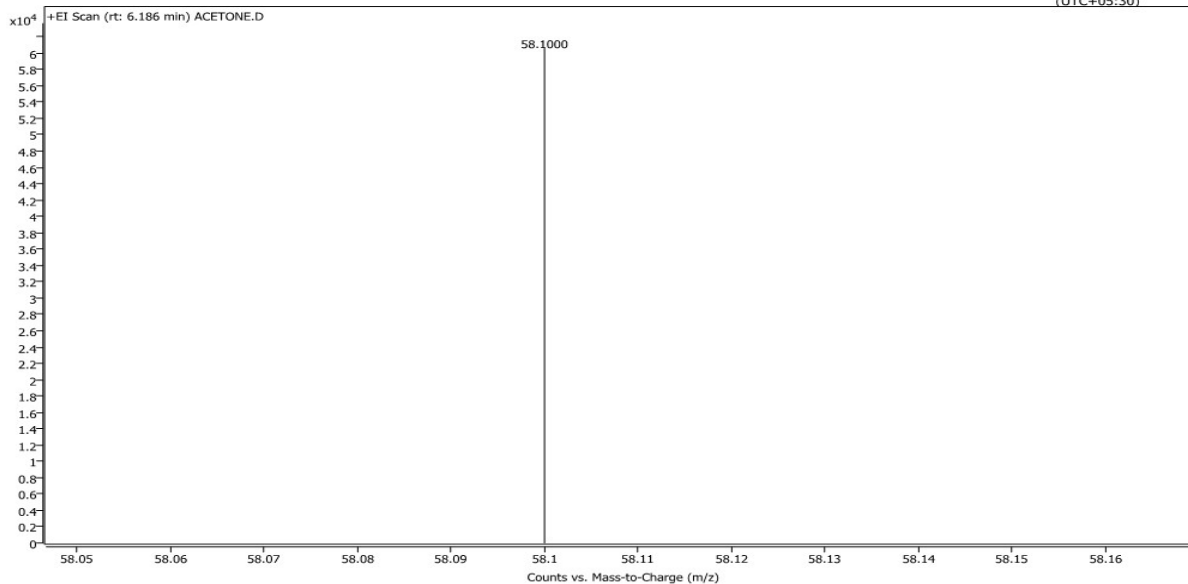
RM-A-002-1\_proton-1-2.jdf  
036623



The Material confirms to 1H-NMR

### Mass (By GCMS):

| Name           | ACETONE_SCAN | Rack Pos.    | Instrument        | GCMSMS01 | Operator          | SRDQCPC10\mmsrd12               |
|----------------|--------------|--------------|-------------------|----------|-------------------|---------------------------------|
| Inj. Vol. (ul) | 1            | Plate Pos.   | IRM Status        |          |                   |                                 |
| Data File      | ACETONE.D    | Method (Acq) | ACETONE_SCAN_00.M |          | Acq. Time (Local) | 01-06-2026 17:15:18 (UTC+05:30) |



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 General requirement for the competence of testing and Calibration Laboratories.

**Safety Information**

Refer to the material safety data sheet.

(-----)  
**Approving Officer**

**Address:** Sabiha Research and Development Ltd. RMP DIVISION Derabassi S.A.S Nagar, Plot 7 First floor Village Bhagwanpur. **Contact detail:** 9876471976; **Email:** sabiharesearchrmp@ gmail.com, **web:** [www.sabiharesearchlab.com](http://www.sabiharesearchlab.com)