TÜBİTAK
ULUSAL METROLOJİ ENSTİTÜSÜ

TÜBİTAK
UME

Certificate of the Reference Material

Name of the Material : 17-alpha-ethinylestradiol

Material Code : UME CRM 1331

Issue Date : 31.10.2025

Revision Date : 31.10.2025 (Revision history can be found on the last page)

Validity Period of the Certificate : 6 months from the sales date

Certified Values :

	Mass Fraction (mg/g)	
Parameter	**Certified Value [1,2]**	**Uncertainty [2,3]**
17-alpha-ethinylestradiol	969	20

[1] The certified value was determined by quantitative nuclear magnetic resonance (qNMR) and mass balance approach methods. In the mass balance approach method, impurities were analysed by a high-performance liquid chromatography with corona-charged aerosol detector (HPLC-CAD), a Karl-Fischer titrator, a head-space-gas chromatography-flame ionization detector (HS-GC-FID) and a thermogravimeter (TGA).

[2] The certified values and uncertainties are traceable to the International System of Units (SI).

[3] The expanded uncertainty of certified value includes characterization, homogeneity, stability components and is stated as the standard uncertainty of measurement multiplied by the coverage factor k=2, which for a normal distribution corresponds to a coverage probability of approximately 95 %. The standard uncertainty of measurement has been determined in accordance with GUM “Guide to the Expression of Uncertainty in Measurement”.

Sales Date

Assoc. Prof. Mustafa ÇETİNTAŞ
Director

TÜBİTAK Gebze Yerleşkesi PK 54 41470 Gebze-Kocaeli /TÜRKİYE T +90 262 679 50 00 F +90 262 679 50 01 www.ume.tubitak.gov.tr

Description

The material is approximately 250 mg 17-alpha-ethinylestradiol in powder form in an amber glass vial. Detailed information about the preparation of the material can be found in the certification report.

Intended Use

This material is intended to be used as a calibration standard for determination of 17-alpha-ethinylestradiol.

Instructions for Use

Before opening the bottle, it should be allowed to equilibrate with the ambient temperature. The material is hygroscopic and all precautions should be taken to prevent contamination and moisture uptake.

The homogeneity of the material has been proven by within-bottle and between-bottle homogeneity tests. The minimum amount of sample to be used is recommended as 20 mg.

This material can be safely dispatched under conditions where the temperature does not exceed 25 °C for up to 2 weeks.

Storage Conditions

The material should be stored at (20 ± 2) °C before and after use.

TÜBİTAK UME cannot be held responsible for changes that might happen to the material at customer's premises due to noncompliance with the instructions for use, and the storage conditions given in the certificate.

Safety Information

The material is manufactured for laboratory use only. General laboratory precautions should be followed during storage and use of the material. It is recommended to handle and dispose of the material according to the existing safety guidelines where applicable. Please refer to the Safety Datasheet (SDS) before any use of the material.

Participants

Information about the laboratory participated in the characterization study is given in the table below.

Laboratory	Address
TÜBİTAK UME	TÜBİTAK Gebze Yerleşkesi, Barış Mahallesi, Dr. Zeki Acar Caddesi No.1, 41470 Gebze - Kocaeli / Türkiye

Methods and/or Techniques Used for the Determination of the Certified Values

Methods and/or techniques used in the characterisation studies are given in the following table.

Method/Technique	Parameter
Quantitative nuclear magnetic resonance (qNMR)	Purity
High-performance liquid chromatography with corona-charged aerosol detector (HPLC-CAD)	
Coulometric Karl Fisher (cKFT)	
Head-space-gas chromatography-flame ionization detector (HS-GC-FID)	
Thermogravimetric analysis (TGA)	

Revision History

Date	Remarks
31.10.2025	First publication.