spectracer

Certificate of Analysis

REFERENCE MATERIAL

Lot N: 1162603 Barcode: 61319660 Certification Date: 08.10.2025

Description: Standard solution B (brown) according to 2.2.2. of European Pharmacopoeia

Ref N: OP 005 125

Composition of standard solution

Volume in millilitres (for 10 ml solution):

Primary Yellow Solution	Primary Red Solution	Primary Blue Solution	Hydrochloric acid (10 g/l HCl)
3.00+/-0.09	3.00+/-0.09	2.40+/-0.05	1.60+/-0.03

Raw-materials:

Primary Yellow Solution - 61316768 - 45.0 +/- 0.1 mg/ml FeCl3.6H2O
Primary Red Solution - 61303294 - 59.5 +/- 0.4 mg/ml CoCl2.6H2O
Primary Blue Solution - 61306684 - 62.4 +/- 0.2 mg/ml CuSO4.5H2O
Hydrochloric acid - 61306882 - 10.0 +/- 0.0 g/l HCl

** The reported expanded uncertainty of measurement 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 EA 4/02.*

Metrological traceability:

BAM 42019 LotN BCCJ8132
NIST 3168a LotN 120629
BAM 42019-50G-F LotN BCCJ8132
BAM 93440 LotN BCCK0309

The metrological traceability is assured through calibration by classical volumetric analysis, using standard solutions prepared from a certified reference material traceable to SI of BAM (CRM). All contributions in relation to the preparation of standard solutions are considered when evaluating the uncertainty.
This reference material is produced in water meeting the Ph Eur monograph requirement for Purified Water.
The measurement results are traceable to SI.
All analytical balances used for the preparation of the solution are calibrated yearly under an in-house procedure WQP 5.15.1.3 with class E1 and class E2 analytical weights, traceable to DKD and are daily checked.
Class A laboratory glassware is used.
The results from temperature measurement are traceable to SI. The thermometers used for solution's calibration are calibrated from an ISO 17025 accredited laboratory. The ambient conditions are controlled with a hygrometer calibrated from an ISO 17025 accredited laboratory.

Expiry date: 08.11.2028

Intended use:

For Laboratory Use Only

This RM is intended for:

- The examination of the degree of coloration of liquids related to Ph Eur 2.2.2.
- Validation of analytical methods
- Preparation of reference solutions

This statement is not intended to restrict the use for other purposes.

Instructions for the correct use of this reference material:

This reference material can be used directly. Do not pipette from container.
The bottle should be open for the minimum time required to dispense the solution. After use, the bottle should be tightly recapped and stored under normal laboratory conditions.

Stability and storage:

This RM is with a guaranteed stability until 0.5% of the certified value within its shelf-life. Stability is guaranteed provided that the solution is kept in its original packaging, tightly closed and stored under normal laboratory conditions protected from light.

Hazardous situation:

The normal laboratory safety precautions should be observed when working with this RM. Further details for the handling of this RM are available as safety data sheet.

Level of homogeneity:

This solution was mixed according to an in-house procedure and is guaranteed to be homogeneous.
To ensure sufficient homogeneity of the sample prior to use thoroughly mix by inversion.

Names of certifying officers:

Laboratory: Dinko Gospodinov

Manager: Krassimira Taralova

This certificate has been computer generated and does not signated

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO 33401, ISO 33405,and Eurachem / CITAC Guides

This certificate relates solely to the lot number given above.
All processes (including generating of this certificate) are completely controlled by the specialized Computer-Aided-Manufacturing (CAM) software.

This Reference Material was produced under a quality management system that is:
- Registered to ISO 9001 - Quality Management System (Lloyd's Register Quality Assurance Ltd Cert No 0039638)
- Accredited according to ISO/IEC 17025
- Accredited according to ISO 17034

Signed by: Taralova, Chemical Production Manager