



# Certificate of Analysis

## CERTIFIED REFERENCE MATERIAL

### Turbidity Standard 4000NTU (Formazin) Primary opalescent suspension

Lot N: 1007398  
Barcode: 61306318

Ref N: OP 001 100

Certification Date: 23.05.2024

| Certified Value* (NTU) | Uncertainty** (NTU) |
|------------------------|---------------------|
|------------------------|---------------------|

|      |        |
|------|--------|
| 4000 | +/- 38 |
|------|--------|

\* The certified value was obtained using Turbidimeter calibration acc. to in-house procedure WQP 5.15.1/29

\*\* 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:

The metrological traceability is assured through calibration on Turbidimeter. The calibration curve is drawn using standard solutions prepared gravimetrically. All contributions in relation to the preparation of standard solutions are considered when evaluating the uncertainty.

This certified reference material is produced by dissolving reagent grade Hydrazine Sulphate and Hexamethylenetetraamine in 18 MOhm deionized water (filtered through a 0.22  $\mu$ m filter).

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 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:** 23.12.2024

**Storage Conditions:** Store under normal laboratory conditions, at temperatures between 15°C to 25°C

#### Intended use: For Laboratory Use Only

This CRM is intended for:

- Calibration of turbidimeters.
- Validation of analytical methods
- Preparation of "working reference samples"
- Detection limit and linearity studies

This standard also meets the requirements of the European Pharmacopoeia on a "2.2.1. Clarity and degree of opalescence of liquids" and ISO 7027-1 "Water quality - Determination of turbidity - part 1: Quantitative methods"

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

#### Instructions for the correct use of this reference material:

Calibrate your instrument as directed by the manufacturer. Ensure that the solution is tempered to normal temperature (20-25°C) and thoroughly mixed prior to analysis. To mix invert bottle gently several times, do not shake. Shaking adds air to the sample and may cause erroneous results.

**Stability and storage:**

This CRM is with a guaranteed stability until  $\pm 0.5\%$  of the certified value within its shelf-life. Stability is guaranteed, provided that the solution is kept in its original packaging, tightly closed stored, as written in the section: Storage Conditions. According to an in-house procedure the producer will monitor this CRM at appropriate intervals and the purchasers will be notified of any significant changes resulting in recertification or with withdrawal of the CRM during the state period of the validity of the certificate.

**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 signed

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO Guide 31, ISO Guide 35, 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 Certified 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

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Signed by: , Chemical Production Manager