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Certificate of Analysis

Nicotinic acid absorbance / transmission standard 18 mg/l linearity standards @ 213 and 261 nm (conforms to Ph Eur and USP)

Lot N: XXXXXX **Barcode:** XXXXXXXX **Certification Date:** XXXXXXXXXX

Ref N:	UV2225NA18.L1
Definition:	This product conforms to the specifications given in 2.2.25 of the European Pharmacopoeia and USP
Description:	Solution of 18 mg/l Nicotinic acid R in 0.1 M Hydrochloric acid for the control of photometric linearity at 213 and 261 nm
Absorbance at 213 nm:	18 mg/l - 0.778 AU
Absorbance at 261 nm:	18 mg/l - 0.758 AU
	Measured values are at 20 +/- 1°C Path length: 10 +/- 0.016 nm
Instrument Qualification:	The spectrophotometer is checked prior to use for: Control of wavelengths: Ref N UV2225WL (Holmium Oxide Solution for Wavelenghts Control acc. 2.2.25 of Ph Eur) Control of absorbance: Ref N UV2225PDB (Set of 2x10 ml Potassium Dichromate Solution for Absorbance Control 235 - 350 nm and 6x10 ml blank acc. 2.2.25 of Ph Eur (old edition) Limit of stray light: Ref N UV2225KCl (Potassium Chloride Solution for Stray Light Limit acc. 2.2.25 of Ph Eur)
Concept of Certification and traceability statement:	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 Property of the result of a measurement whereby it can be related to stated references, usually national or international standards, trough an unbroken chain of comparisons all having stated uncertainties (ISO VIM [5]). 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 SI (DKD) and are checked daily. Class A laboratory glassware is used. The vernier caliper used for the cuvette check is calibrated from an ISO 17025 accredited laboratory. 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:	XXXXXX
Intended use:	For Laboratory Use Only Control of linearity of UV/VIS spectrophotometer Validation of analytical methods Preparation of "working reference samples" Detection limit and linearity studies These statements are not intended to restrict the use for other purposes.

DOMINIQUE DUBSCHER SAS

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Instructions for the correct use of this reference material: for direct use only

Set the spectrophotometer to measure absorbance at 213 nm. Fill a cell with Blank (refer to ampoule labelling), and autozero the spectrophotometer. Fill a cell consecutively with the solutions from the set, and record the absorbance. Repeat the process at 261nm.

Stability and storage:

This product 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, stored in a refrigerator. According to an in-house procedure the producer will monitor this product at appropriate intervals and the purchasers will be notified of any significant changes resulting in recertification or with withdrawal of the product during the state period of the validity of the certificate.

Hazardous situation:

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

Level of homogeneity:

This product 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: Dino Mitev

Manager: Krassimira Taralova

This product 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

[1] ISO Guide 31: Reference materials - Contents of certificates and labels
[2] ISO Guide 35: Reference materials - General and statistical principles for certification
[3] EURACHEM/CITAC Guide: Quantifying Uncertainty in Analytical Measurement
[4] EA 4/02: Expression of the Uncertainty of Measurement in Calibration
[5] ISO/IEC Guide 99: International Vocabulary of Metrology-Basic and general concepts and associated terms (VIM)
[6] ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
[7] ISO 17034: General Requirements for the Competence of Reference Material Producers

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.

Signed by: Taralova, Chemical Production Manager

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