

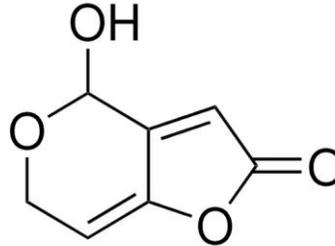
Reference Material

This certificate has been created in compliance with ISO/IEC 17034. The reference material has been developed, manufactured, and validated in accordance with ISO/IEC 17025, ISO/IEC 17034, and a certified quality management system. LVA GmbH is accredited by the Austrian accreditation body as a recognized reference material producer in line with ISO/IEC 17034.

Product Name

Patulin 100 µg/mL in Acetonitrile, Solution of Patulin in Acetonitrile

Item Number VE00008367
Lot Number PAT202503001
CAS No. 149-29-1
Mol. Weight 154.12 g/mol
Mol. Formula C7H6O4
Expiry Date 05.09.2026
Storage Temp ≤ -18 °C
Format Solution
Volume (ml) 2.5



CERTIFIED Concentration 100,0 µg/mL	CERTIFIED Expanded Uncertainty (U) 2,331 µg/mL
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Metrological Traceability

This mycotoxin standard is produced gravimetrically for precise concentration determination, calculated by dividing the mass of the raw material, adjusted for purity, by the solvent volume to yield a final concentration in µg/mL. Raw materials, with a minimum purity of 90% verified via q-NMR by an external ISO/IEC 17025-accredited lab, are weighed on ISO/IEC 17025-compliant precision balances using traceable weights. Solvents are stabilized at room temperature monitored by traceable thermometers. All calibration and measurement protocols are documented to ensure traceable and reproducible results, with final processing at the LVA site in

Associated Uncertainty

The mathematical representation of the u_{CRM} calculation is as follows: $u_{CRM} = \sqrt{u_{prep}^2 + u_{bb}^2 + u_{lts}^2 + u_{sts}^2}$

u_{CRM} is calculated from the uncertainty contributions of the gravimetric preparation (u_{prep}), the measurement between units (u_{bb}), the long-term stability (u_{lts}), and the short-term stability (u_{sts}). This combined uncertainty is then expanded by a factor of $k = 2$, resulting in the expanded uncertainty U , which accompanies the certified value as a \pm indication. The summation of uncertainty values is done in absolute terms (in µg/mL).

Homogeneity Assessment

Homogeneity was evaluated following the guidelines outlined in ISO 33405:2024. Random stratified sampling protocol was employed to sample completed units. The chemical analysis results were subsequently subjected to Single Factor Analysis of Variance (ANOVA). The uncertainty attributed to homogeneity was determined from the ANOVA and no heterogeneity was observed.

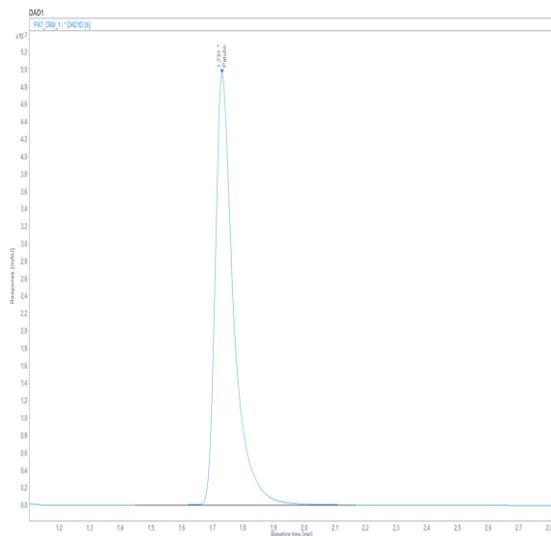
Stability Assessment

The stability assessment includes both short-term and long-term evaluations, simulating transportation and storage conditions for the sales units. The short-term stability study was conducted at room temperature over a period of 5 weeks, while the long-term stability was assessed according to the specified storage conditions until the expiry date. Additionally, long-term monitoring is conducted for each released batch throughout its shelf life.

CERTIFIED BY	CERTIFIED ON		VERSION
Dr. D. Steiner	5 Jun 2025		FM-LVA-0516 Rev. 3.0

* Head of Department

CHROMATOGRAM



Instrument
HPLC-System Agilent 1200

Detection
DAD

Column
Kinetex 2,6 µm, 100 x 3 mm

Inj.-Vol.
20 µl

Flow
0,5 ml/min

Measurement Method

The assigned value is derived from a purity determination and gravimetrically prepared value.

Purity Determination

Purity was determined by an external ISO/IEC 17025 laboratory following quantitative NMR analysis.

Method for Quality Release

HPLC-DAD/FLD, MS, NMR

Eluent A: H3PO4 0,1%
 Eluent B: Acetonitrile
 Eluent A->B: 14 min
 Oven 35 °C
 Sample dilution 1:10 with water
 DAD setting 274 nm
 23°C room temperature

Solvent Information

Solvent: Acetonitrile, 241104031, 100 mL.

Raw Material Name	Lot No.	Purity %	U %
Patulin	PATLVA01	99,18	0,21

Health and Safety Information

All chemical reference materials should be treated as potentially hazardous and utilized exclusively by qualified laboratory personnel. Please consult the Safety Data Sheet for comprehensive details regarding any hazards and the necessary precautions to be observed.

Intended Use

Designed for utilization in a laboratory setting as a standard for calibration and quality control, or for method development in analytical techniques. Not intended for drug, household, or other applications.

Storage

The reference material should be kept in its original sealed container at the specified temperature.

Instructions for Handling and correct Use

The internal pressure of the container may vary slightly from the atmospheric pressure at the user's location. Open the container slowly and with caution to prevent material dispersion.

Procedure in Scope of Accreditation

This certificate has been issued in accordance with the procedure documented in DK-LVA-0471 "Referenzmaterialproduktion", with the issue date of 27 November 2024, as defined within the scope of accreditation.