

Certificate of Analysis

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672959 Lot: 828122

Gentamicin sulfate salt hydrate

9.40 % (g/g)

1. General Information

Formula Expiry Date 01 Oct 2028

Mol. Weight 0.00 g/mol Store at 4°C (in the dark)

CAS-No. 1405-41-0

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 90.26 % (g/g) Expanded Uncertainty 1.83 % (g/g)

Assay Purity (HPLC) 99.62 % (g/g) Uncertainty 0.38 % (g/g)

contains sulfate: 29,0% Gentamicin C1 27.7% Gentamicin C1a 27.1% Sum of C2+C2a 45.2%

Water

Certified on 09 Oct 2024

by Jacqueline Seidel RM Release

The overall purity is calculated by: Purity(%) = Assay purity*(100-water content-impurities)/100 For non-specified hydrates, the overall purity refers to the stated molecular formula.

The reported uncertainties are determined in accordance with ISO 17034 with a 95% confidence level (k=2). The Uncertainty is based on the combined uncertainties, including uncertainties of characterization and stability testing. The expiry date is based on the current knowledge and holds only for proper storage conditions in the originally closed flask. If the substance is proven to be unstable under the given storage conditions, you will be contacted immediately. The warranty of this product is limited to the purchasing price of this product and to the first point of use. The indicated long-term storage temperature can vary in a range of \pm 4 °C.

Our standards are for laboratory use only and can be used as reference material for calibration of chromatographic systems or related analytical techniques. For handling instructions see the MSDS. A minimum sample of 2 mg is recommended. Deploying less material will increase the uncertainty by a factor 2 for half of sample and 4 for a quarter of sample. The material in the vial can be used multiple times, but it is strongly recommended that all external negative influences to the material are considered and ruled out (e.g. high temperatures, UV-radiation, moisture, oxygen). It is strongly recommended to open the vial at room temperature only and handle the material under inert gas if necessary. The integrity of the purity cannot be guaranteed if the substance is handled under unfavorable conditions.

The balances used are calibrated with weights traceable to the national standards (DKD).

HPC Standards GmbH produces reference materials according to ISO 17034. For further information, check:



HPC Standards GmbH

HPLC-Method

Article 672959 Lot-No. 828122

Column L=100mm, ID=4.6mm; Kinetex C18, 100A, 2.6µm

Eluent A Acetonitrile + 0.1% Formic acid Eluent B Water + 0.1% Formic acid

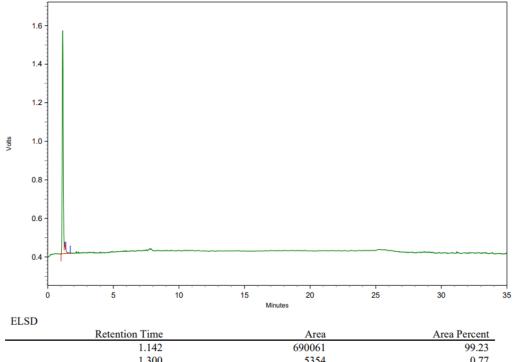
Gradient %A %В time

0 0min 100 19min 90 10 25min 90 10

Flow 0.9 ml min-1

ELSD Detector Injection-Volume 5 µl

Sample 1.0 mg ml-1 (Water)



Retention Time	Area	Area Percent
1.142	690061	99.23
1.300	5354	0.77

Totals

Exemplary chromatogram of given method.

	Version	Article	Lot	Reason for Change	Date
Ī	1	672959	828122	Initial Version	09 Oct 2024
	2	672959	828122	Data Update	09 Oct 2024