

672959**Lot: 805560****Gentamicin sulfate salt hydrate**1. General Information

Formula		Expiry Date	01 Oct 2025
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	92.20 % (g/g)	Expanded Uncertainty	0.60 % (g/g)
Assay Purity (HPLC)	98.51 % (g/g)	Uncertainty	0.19 % (g/g)
Water	6.41 % (g/g)		
Gentamicin C1	26.0%		
Gentamicin C1a	27.6%		
Sum of C2+C2a	46.4%		
Sulfate	30.6%		
Water	6.41%		

Certified on 05 Oct 2021



by Jan Heumann

The overall purity is calculated by: $\text{Purity}(\%) = \frac{\text{Assay purity} \times (100 - \text{water content} - \text{impurities})}{100}$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

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

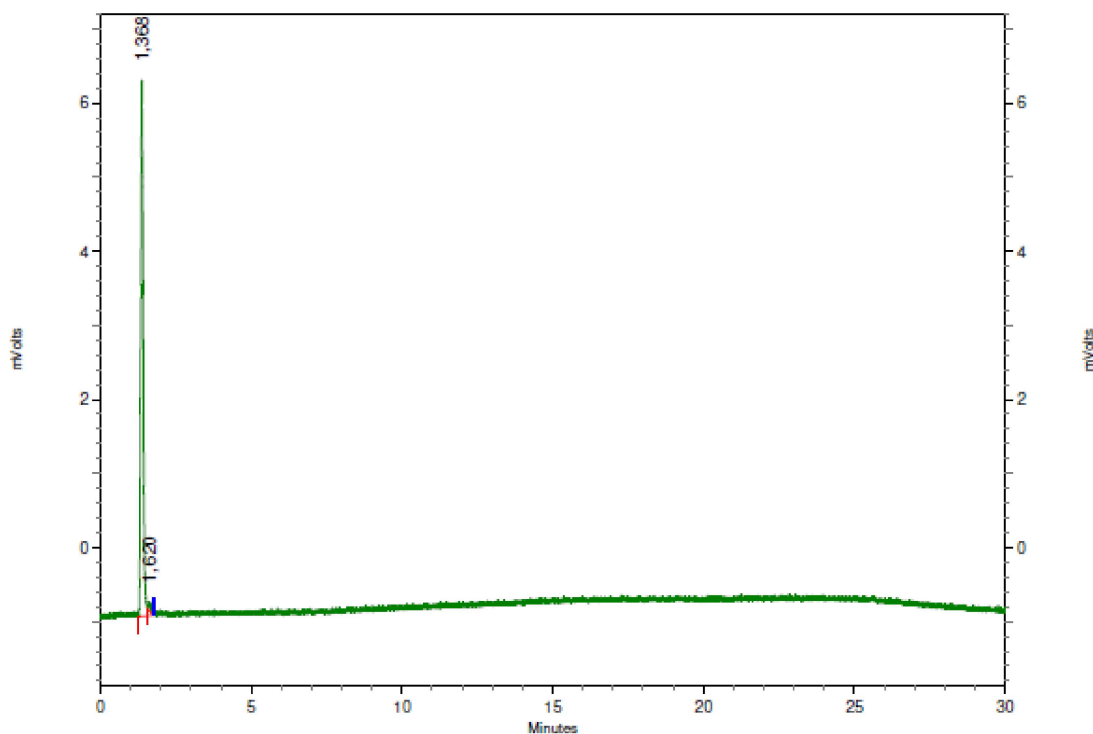
The HPC Standards GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-20844-01-00, has shown competence based on ISO 17034:2017 for production of certified reference materials.

HPLC-Method

Article 672959
 Lot-No. 805560
 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

time	%A	%B
0min	0	100
22.5min	90	10
25min	90	10

Flow 0.7 ml min⁻¹
 Detector ELSD
 Injection-Volume 5 µl
 Sample 1.0 mg ml⁻¹ (Water)



ELSD AD1 -
Analog Board 1
Results

Retention Time	Height	Area	Area Percent
1,368	7230	42718	98,567
1,620	125	621	1,433

Totals	Height	Area	Area Percent
	7355	43339	100,000

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
3.0	672959	805560	Format update	05 Oct 2021

672968	Lot: 796692
Oxytetracycline hydrochloride	

1. General Information

Formula	C ₂₂ H ₂₅ CIN ₂ O ₉	Expiry Date	01 Jul 2025
Mol. Weight	496.89 g/mol	Store at	4°C (in the dark)
CAS-No.	2058-46-0		

2. Batch Analysis

Identity	confirmed by LC-MS		
Overall Purity	91.46 % (g/g)	Expanded Uncertainty	0.66 % (g/g)
Assay Purity (HPLC)	95.22 % (g/g)	Uncertainty	0.17 % (g/g)
Water	3.95 % (g/g)		

Certified on 06 Jul 2020

by Stefanie Selbmann

The overall purity is calculated by: $\text{Purity(\%)} = \frac{\text{Assay purity} \times (100 - \text{water content} - \text{impurities})}{100}$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

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

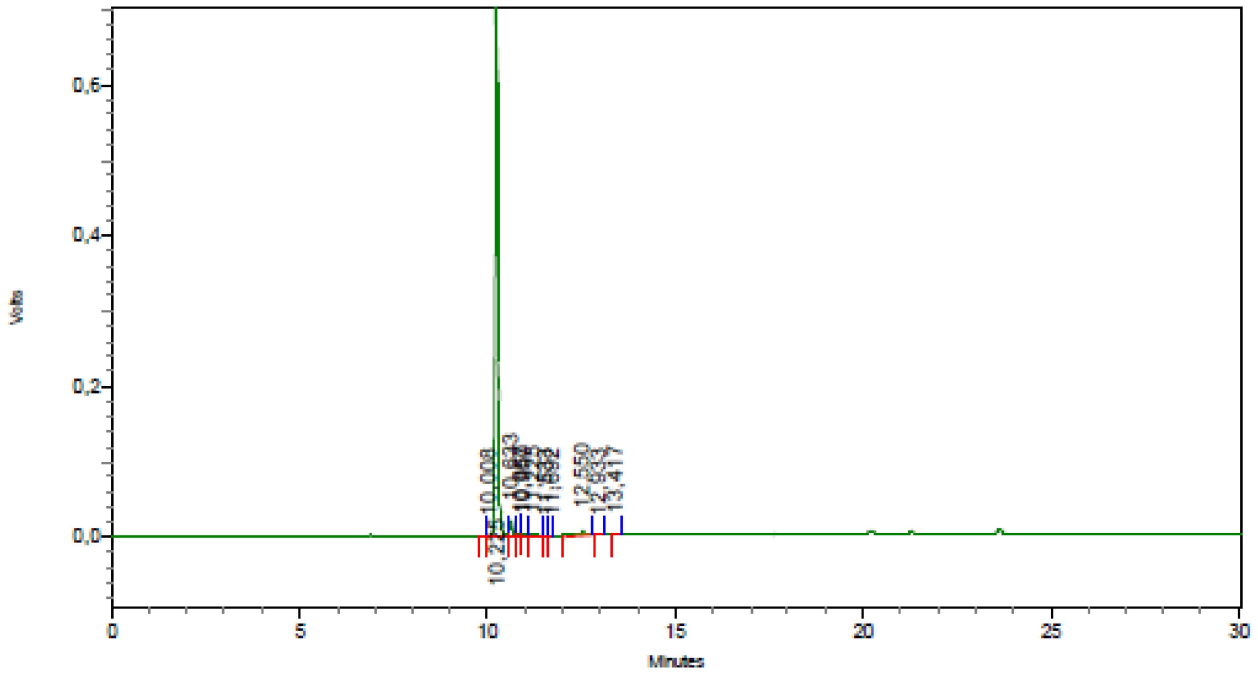
The HPC Standards GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-20844-01-00, has shown competence based on ISO 17034:2017 for production of certified reference materials.

HPLC-Method

Article 672968
 Lot-No. 796692
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient

time	%A	%B
0min	0	100
22.5min	90	10
25min	90	10

Flow 1.0 ml min⁻¹
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 0.5 mg ml⁻¹ (Water)



Detector A - 1 (220nm)

Retention Time	Height	Area	Area Percent
10,008	339	2107	0,05
10,225	707712	4017676	95,21
10,633	19983	102058	2,42
10,867	3924	18890	0,45
10,950	3655	18756	0,44
11,225	1441	14820	0,35
11,533	141	833	0,02
11,692	81	327	0,01
12,550	6539	37802	0,90
12,933	383	3068	0,07
13,417	659	3312	0,08

Totals			
	744857	4219649	100,00

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
1.0.0	672968	796692	Initial Version	06 Jul 2020
1	672968	796692	Text Update	10 Jan 2022
2	672968	796692	correction Overall Purity	25 May 2022

672980**Lot: 803572****Trimethoprim**1. General Information

Formula	C14H18N4O3	Expiry Date	01 Jul 2026
Mol. Weight	290.32 g/mol	Store at	4°C (in the dark)
CAS-No.	738-70-5		

2. Batch Analysis

Identity	confirmed by LC-MS		
Overall Purity	99.57 % (g/g)	Expanded Uncertainty	0.34 % (g/g)
Assay Purity (HPLC)	99.98 % (g/g)	Uncertainty	0.17 % (g/g)
Water	0.10 % (g/g)		
Residual Solvents	0.03 % (g/g)	Uncertainty	0.01 % (g/g)
Inorganic Impurities	0.28 % (g/g)	Uncertainty	0.01 % (g/g)

Certified on 22 Jun 2021



by Jan Heumann

The overall purity is calculated by: $\text{Purity}(\%) = \frac{\text{Assay purity} \times (100 - \text{water content} - \text{impurities})}{100}$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

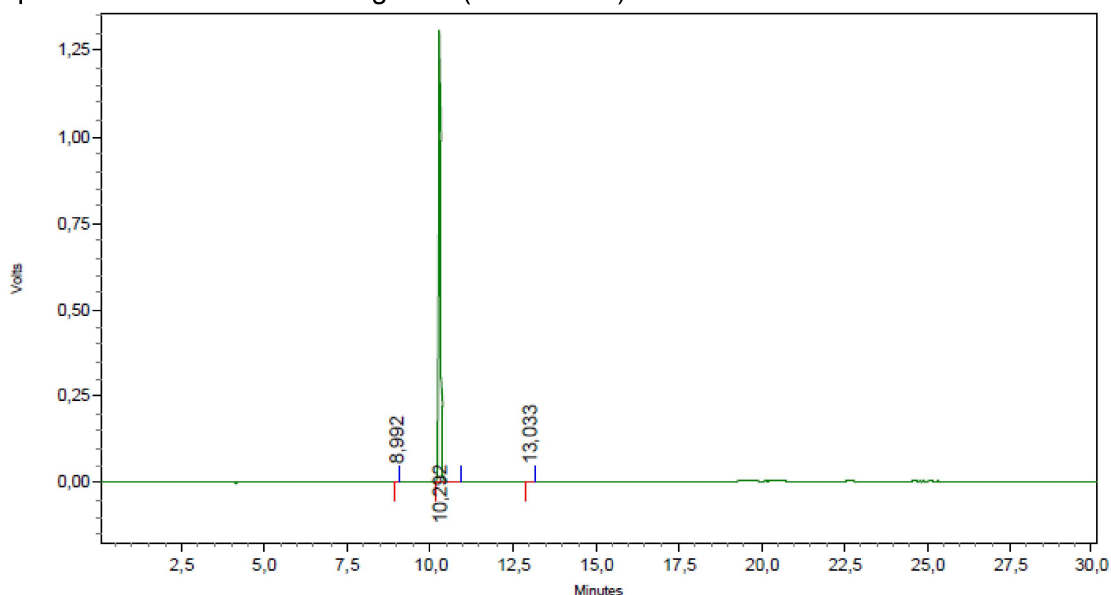
Our standards are for laboratory use only and can be used as reference material for calibration of chromatographic systems or related analytical techniques. For handling instructions see the MSDS. A minimum sample of 2 mg is recommended. Deploying less material will increase the uncertainty. The material 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).

The HPC Standards GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-20844-01-00, has shown competence based on ISO 17034:2017 for production of reference materials in form of organic pure substances and their solutions (for further specification see the annex of the accreditation certificate).

HPLC-Method

Article 672980
 Lot-No. 803572
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient
 time %A %B
 0min 0 100
 22.5min 90 10
 25min 90 10
 Flow 1.0 ml min⁻¹
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 0.2 mg ml⁻¹ (Acetonitrile)



Detector A - 1 (220nm)

Retention Time	Height	Area	Area Percent
8,992	106	606	0,01
10,292	1307752	7085630	99,98
13,033	111	684	0,01

Totals	1307969	7086920	100,00
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Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
2.2	672980	803572	Text update	22 Jun 2021

673026 **Lot: 808279**
Amoxicillin trihydrate1. General Information

Formula	C ₁₆ H ₁₉ N ₃ O ₅ S · 3H ₂ O	Expiry Date	01 Feb 2027
Mol. Weight	419.45 g/mol	Store at	4°C (in the dark)
CAS-No.	61336-70-7		

2. Batch Analysis

Identity	confirmed by LC-MS		
Overall Purity	98.97 % (g/g)	Expanded Uncertainty	0.96 % (g/g)
Assay Purity (HPLC)	98.88 % (g/g)	Uncertainty	0.17 % (g/g)
Water	12.80 % (g/g)	Uncertainty	0.45 % (g/g)
Water (theor.)	12.89 % (g/g)		
Excess Water	-0.09 % (g/g)		

Certified on 08 Feb 2022



by Jan Heumann

The overall purity is calculated by: $\text{Purity}(\%) = \frac{\text{Assay purity} \cdot (100 - \text{water content} - \text{impurities})}{100}$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

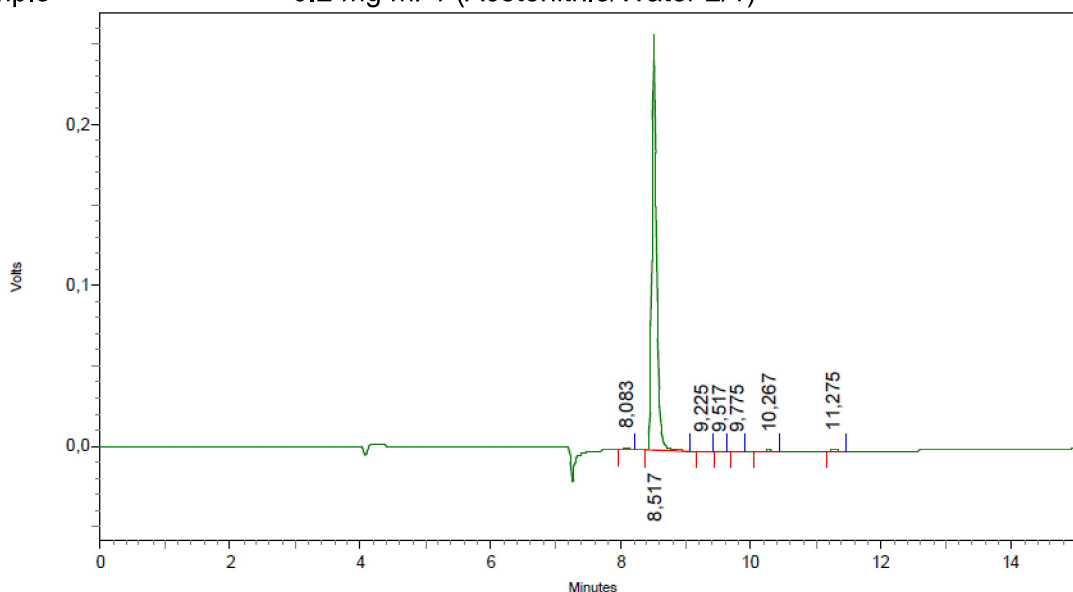
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The balances used are calibrated with weights traceable to the national standards (DKD).

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HPLC-Method

Article 673026
 Lot-No. 808279
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1% Phosphoric acid (Water)
 Gradient
 time %A %B
 0min 0 100
 22.5min 90 10
 25min 90 10
 Flow 1.0 ml min⁻¹
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 0.2 mg ml⁻¹ (Acetonitrile/Water 2/1)



Detector A - 1 (220nm)

Retention Time	Height	Area	Area Percent
8,083	1522	7713	0,56
8,517	257601	1357853	98,90
9,225	92	852	0,06
9,517	54	269	0,02
9,775	42	293	0,02
10,267	197	1219	0,09
11,275	899	4804	0,35

Totals	260407	1373003	100,00
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Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
1	673026	808279	Initial Version	08 Feb 2022

673115**Lot: 814303****Thymol**1. General Information

Formula	C ₁₀ H ₁₄ O	Expiry Date	01 Dec 2027
Mol. Weight	150.22 g/mol	Store at	20°C (in the dark)
CAS-No.	89-83-8		

2. Batch Analysis

Identity	confirmed by GC-MS		
Overall Purity	99.97 % (g/g)	Expanded Uncertainty	0.34 % (g/g)
Assay Purity (HPLC)	99.97 % (g/g)	Uncertainty	0.17 % (g/g)

Certified on 21 Nov 2022



by Jacqueline Seidel

The overall purity is calculated by: $\text{Purity}(\%) = \text{Assay purity} \cdot (100 - \text{water content} - \text{impurities}) / 100$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

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

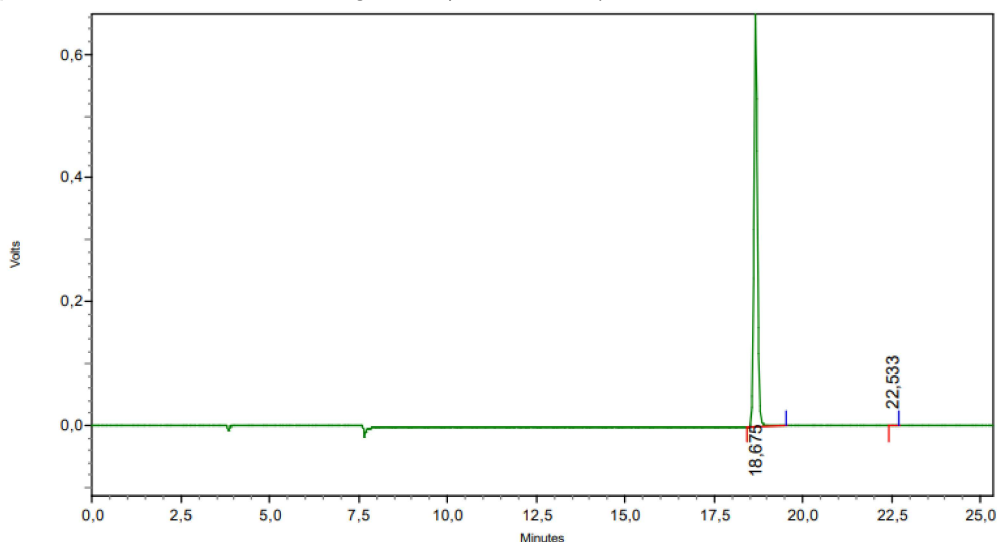
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HPLC-Method

Article 673115
 Lot-No. 814303
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient

time	%A	%B
0min	0	100
22.5min	90	10
25min	90	10

Flow 1.0 ml min-1
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 0.3 mg ml-1 (Acetonitrile)



Detector A - 1 (220nm)

Retention Time	Height	Area	Area Percent
18,675	691684	4165586	99,96
22,533	270	1764	0,04

Totals	Height	Area	Area Percent
	691954	4167350	100,00

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
1	673115	814303	Initial Version	21 Nov 2022

674759**Lot: 812034****Florfenicol**1. General Information

Formula	C ₁₂ H ₁₄ Cl ₂ FNO ₄ S	Expiry Date	01 Aug 2027
Mol. Weight	358.21 g/mol	Store at	4°C (in the dark)
CAS-No.	73231-34-2		

2. Batch Analysis

Identity	confirmed by LC-MS		
Overall Purity	99.36 % (g/g)	Expanded Uncertainty	0.34 % (g/g)
Assay Purity (HPLC)	99.36 % (g/g)	Uncertainty	0.17 % (g/g)

Certified on 04 Aug 2022

by Corinna Gröst

The overall purity is calculated by: $\text{Purity}(\%) = \text{Assay purity} \cdot (100 - \text{water content} - \text{impurities}) / 100$

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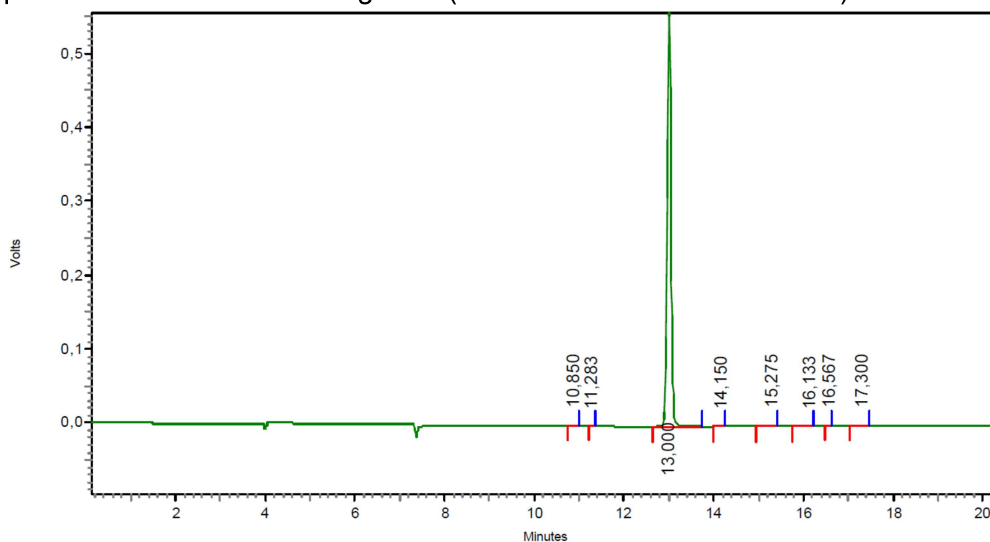
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The balances used are calibrated with weights traceable to the national standards (DKD).

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HPLC-Method

Article 674759
 Lot-No. 812034
 Column L=250mm, ID=4.6mm; Reprosil-PUR C18, 100A, 10µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient
 time %A %B
 0min 0 100
 22.5min 90 10
 25min 90 10
 Flow 1.0 ml min-1
 Detector UV-220nm
 Injection-Volume 20 µl
 Sample 0.3 mg ml-1 (30% Acetonitrile / 70% Water)



Detector A - 1 (220nm)

Retention Time	Height	Area	Area Percent
10,850	889	5267	0,15
11,283	180	875	0,03
13,000	567593	3406860	99,36
14,150	592	3610	0,11
15,275	597	7421	0,22
16,133	72	799	0,02
16,567	107	456	0,01
17,300	373	3522	0,10

Totals	Height	Area	Area Percent
	570403	3428810	100,00

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
1	674759	812034	Initial Version	04 Aug 2022

674878	Lot: 816399
Amprolium hydrochloride	

1. General Information

Formula	C ₁₄ H ₂₀ Cl ₂ N ₄	Expiry Date	01 Feb 2028
Mol. Weight	315.24 g/mol	Store at	20°C (in the dark)
CAS-No.	137-88-2		

2. Batch Analysis

Overall Purity	99.90 % (g/g)	Expanded Uncertainty	1.00 % (g/g)
Assay	99.90 % (g/g)	Uncertainty	0.50 % (g/g)

Certified on 30 Jan 2023



by YingYing Gao

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

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

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Version 1

Version	Article	Lot	Reason for Change	Date
1	674878	816399	Initial Version	30 Jan 2023

674884**Lot: 812652****Diclazuril**1. General Information

Formula	C ₁₇ H ₉ Cl ₃ N ₄ O ₂	Expiry Date	01 Oct 2027
Mol. Weight	407.64 g/mol	Store at	20°C (in the dark)
CAS-No.	101831-37-2		

2. Batch Analysis

Identity	confirmed by LC-MS		
Overall Purity	99.49 % (g/g)	Expanded Uncertainty	0.38 % (g/g)
Assay Purity (HPLC)	99.49 % (g/g)	Uncertainty	0.19 % (g/g)

Certified on 16 Sep 2022

by Corinna Gröst

The overall purity is calculated by: $\text{Purity}(\%) = \text{Assay purity} \cdot (100 - \text{water content} - \text{impurities}) / 100$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

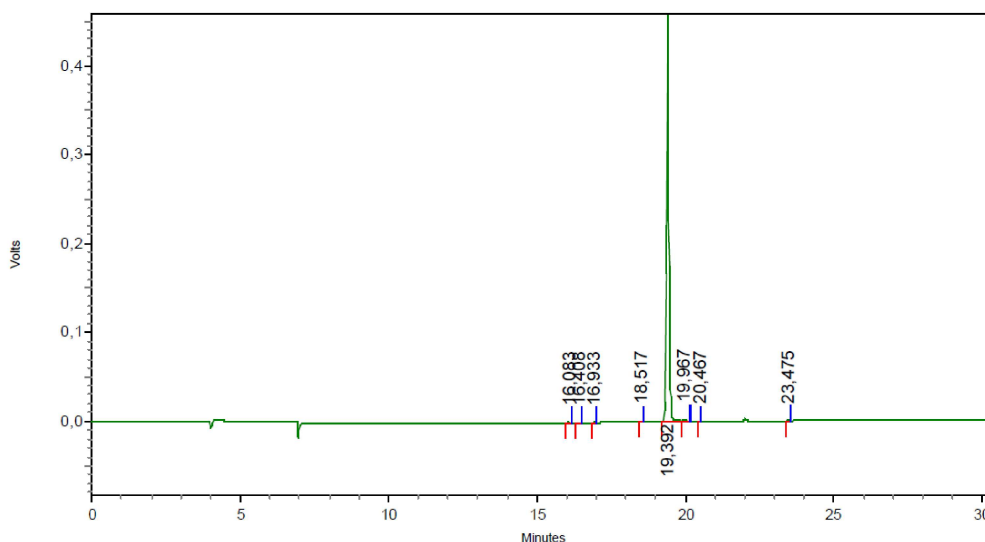
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The balances used are calibrated with weights traceable to the national standards (DKD).

The HPC Standards GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-20844-01-00, has shown competence based on ISO 17034:2017 for production of certified reference materials.

HPLC-Method

Article 674884
 Lot-No. 812652
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient
 time %A %B
 0min 0 100
 22.5min 90 10
 25min 90 10
 Flow 1.0 ml min-1
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 0.1 mg ml-1 (Acetonitrile)



Detector A - 1 (220nm)

Retention Time	Height	Area	Area Percent
16.083	592	3184	0.12
16.408	173	974	0.04
16.933	150	834	0.03
18.517	55	248	0.01
19.392	457217	2751620	99.55
19.967	1027	5984	0.22
20.467	147	722	0.03
23.475	125	607	0.02

Totals	Height	Area	Area Percent
	459486	2764173	100.00

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
1	674884	812652	Initial Version	16 Sep 2022

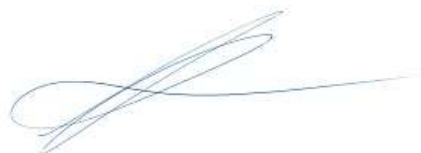
674886**Lot: 803829****Fenbendazole**1. General Information

Formula	C ₁₅ H ₁₃ N ₃ O ₂ S	Expiry Date	01 Jul 2026
Mol. Weight	299.35 g/mol	Store at	20°C (in the dark)
CAS-No.	43210-67-9		

2. Batch Analysis

Identity	confirmed by LC-MS		
Overall Purity	99.94 % (g/g)	Expanded Uncertainty	0.34 % (g/g)
Assay Purity (HPLC)	99.94 % (g/g)	Uncertainty	0.17 % (g/g)

Certified on 05 Jul 2021



by Jan Heumann

The overall purity is calculated by: $\text{Purity}(\%) = \text{Assay purity} \cdot (100 - \text{water content} - \text{impurities}) / 100$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

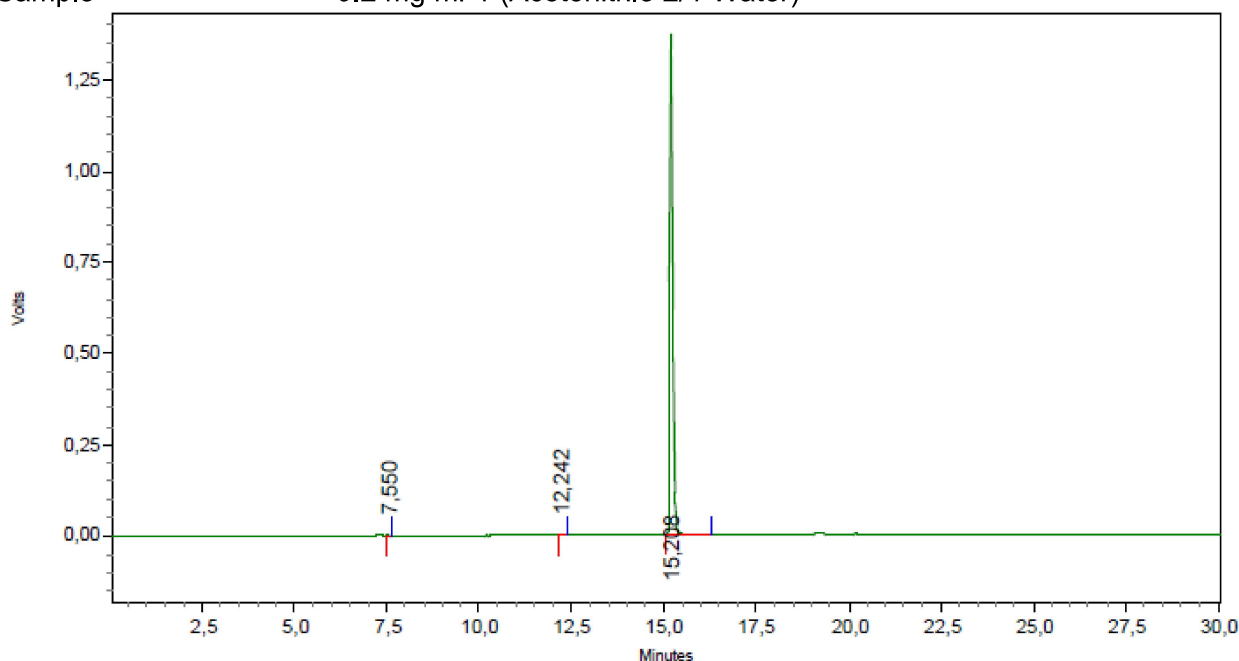
Our standards are for laboratory use only and can be used as reference material for calibration of chromatographic systems or related analytical techniques. For handling instructions see the MSDS. A minimum sample of 2 mg is recommended. Deploying less material will increase the uncertainty. The material 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).

The HPC Standards GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-20844-01-00, has shown competence based on ISO 17034:2017 for production of reference materials in form of organic pure substances and their solutions (for further specification see the annex of the accreditation certificate).

HPLC-Method

Article 674886
 Lot-No. 803829
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient
 time %A %B
 0min 0 100
 22.5min 90 10
 25min 90 10
 Flow 1.0 ml min-1
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 0.2 mg ml-1 (Acetonitrile 2/1 Water)



Detector A - 1 (220nm)

Retention Time	Height	Area	Area Percent
7,550	538	2553	0,03
12,242	382	2111	0,03
15,208	1370186	7926654	99,94

Totals			
	1371106	7931318	100,00

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
2.2	674886	803829	Text update	05 Jul 2021

674893**Lot: 810376****Enrofloxacin**1. General Information

Formula	C19H22FN3O3	Expiry Date	01 May 2025
Mol. Weight	359.40 g/mol	Store at	20°C (in the dark)
CAS-No.	93106-60-6		

2. Batch Analysis

Identity	confirmed		
Overall Purity	99.60 % (g/g)	Expanded Uncertainty	0.50 % (g/g)
Assay Purity (HPLC)	99.60 % (g/g)	Uncertainty	0.25 % (g/g)

Certified on 13 May 2020



by Heike Uhlig

The overall purity is calculated by: $\text{Purity}(\%) = \text{Assay purity} \cdot (100 - \text{water content} - \text{impurities}) / 100$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

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

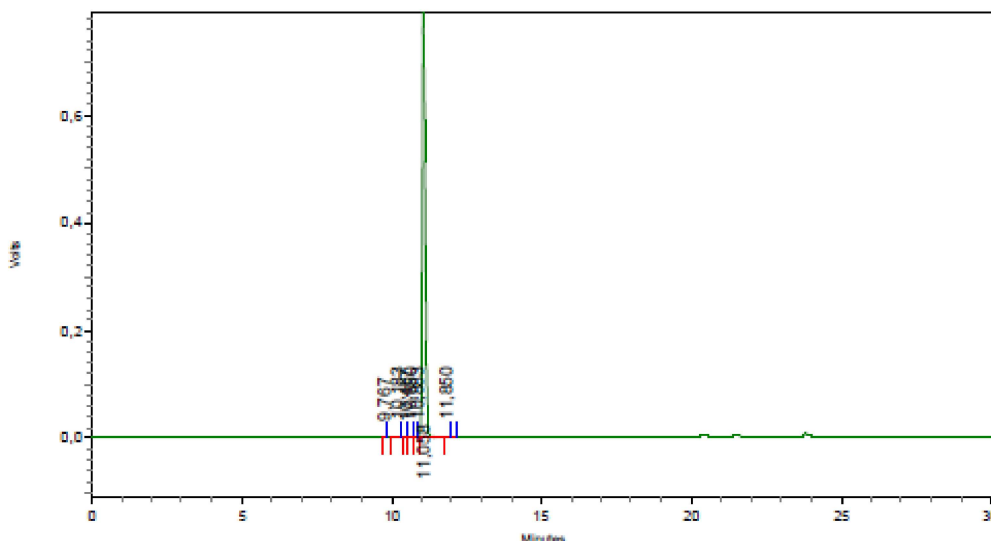
The HPC Standards GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-20844-01-00, has shown competence based on ISO 17034:2017 for production of certified reference materials.

HPLC-Method

Article 674893
 Lot-No. 810376
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient

time	%A	%B
0min	0	100
22.5min	90	10
30min	90	10

Flow 1.0 ml min⁻¹
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 0.5 mg ml⁻¹ (Acetonitrile)



Detector A - 1 (220nm)			
Retention Time	Height	Area	Area Percent
9,767	98	444	0,01
10,183	1550	7530	0,15
10,467	36	139	0,00
10,650	333	1390	0,03
10,883	27	324	0,01
11,058	815396	4993153	99,59
11,850	2127	10662	0,21
Totals		5013642	100,00

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
1	674893	810376	Initial Version	13 May 2020

675916 Lot: **813568**
Cloxacillin sodium salt hydrate

1. General Information

Formula	C ₁₉ H ₁₇ CIN ₃ NaO ₅ S	Expiry Date	01 Nov 2027
Mol. Weight	457.86 g/mol	Store at	4°C (in the dark)
CAS-No.	7081-44-9		

2. Batch Analysis

Identity	confirmed by LC-MS		
Overall Purity	96.09 % (g/g)	Expanded Uncertainty	0.40 % (g/g)
Assay Purity (HPLC)	96.86 % (g/g)	Uncertainty	0.20 % (g/g)
Water	0.79 % (g/g)		

Certified on 17 Oct 2022



by Jacqueline Seidel

The overall purity is calculated by: $\text{Purity}(\%) = \frac{\text{Assay purity} \cdot (100 - \text{water content} - \text{impurities})}{100}$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

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

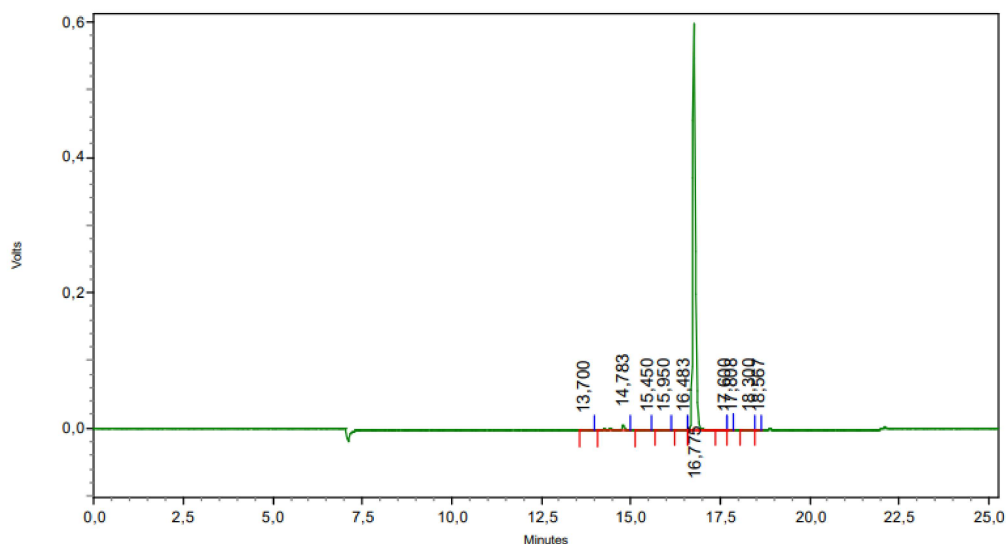
The HPC Standards GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-20844-01-00, has shown competence based on ISO 17034:2017 for production of certified reference materials.

HPLC-Method

Article 675916
 Lot-No. 813568
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient

time	%A	%B
0min	0	100
22.5min	90	10
25min	90	10

Flow 1.0 ml min-1
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 0.3 mg ml-1 (Water)



Detector A - 1 (220nm)

Retention Time	Height	Area	Area Percent
13,700	362	2939	0,08
14,783	8114	85335	2,42
15,450	93	1019	0,03
15,950	310	4188	0,12
16,483	230	1778	0,05
16,775	600000	3420599	96,93
17,600	311	4417	0,13
17,808	785	3585	0,10
18,300	260	3169	0,09
18,567	341	1790	0,05

Totals	610806	3528819	100,00
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Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
1	675916	813568	Initial Version	17 Oct 2022

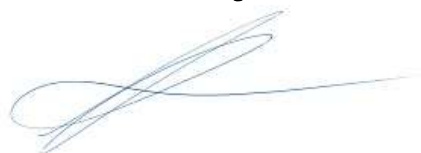
683379**Lot: 804435****Tylosin tartrate**1. General Information

Formula	C50H83NO23	Expiry Date	01 Aug 2025
Mol. Weight	1066.19 g/mol	Store at	4°C (in the dark)
CAS-No.	74610-55-2		

2. Batch Analysis

Identity	confirmed by LC-MS		
Overall Purity	92.63 % (g/g)	Expanded Uncertainty	1.00 % (g/g)
Assay Purity (HPLC)	92.63 % (g/g)	Uncertainty	0.50 % (g/g)

Certified on 04 Aug 2021



by Jan Heumann

The overall purity is calculated by: $\text{Purity}(\%) = \text{Assay purity} \cdot (100 - \text{water content} - \text{impurities}) / 100$

The reported uncertainty U is an expanded uncertainty according to EURACHEM / CITAC guide CG4 – Quantifying Uncertainty in Analytical Measurement. 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.

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

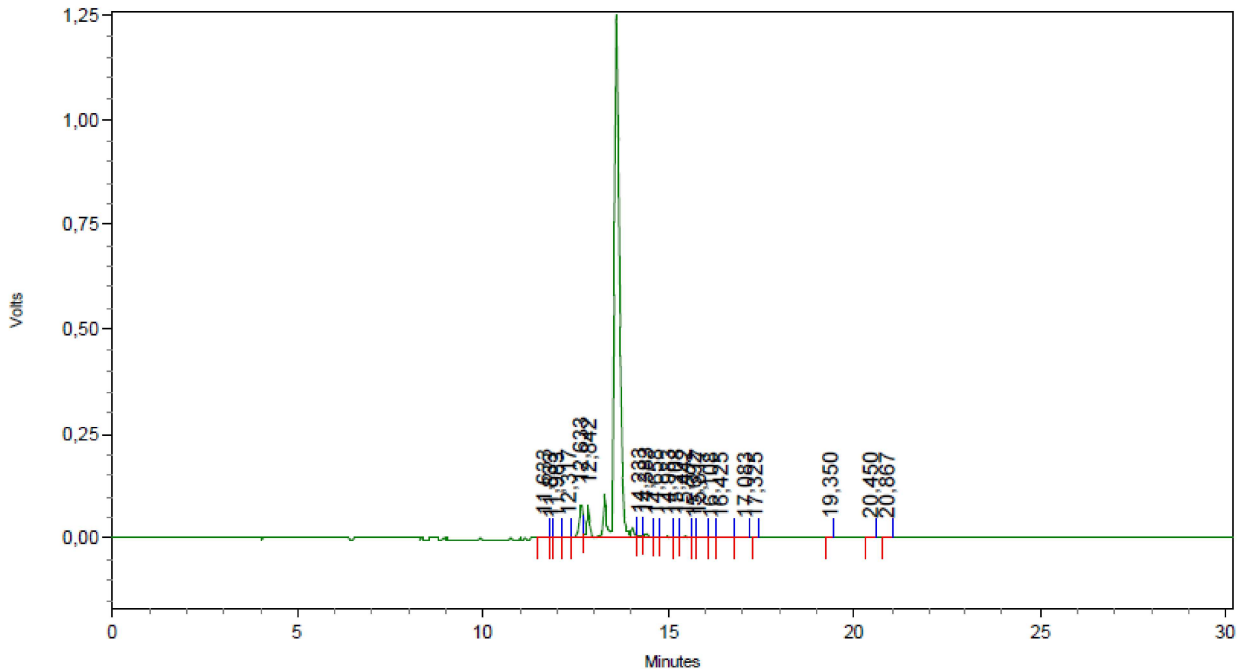
The HPC Standards GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-20844-01-00, has shown competence based on ISO 17034:2017 for production of certified reference materials.

HPLC-Method

Article 683379
 Lot-No. 804435
 Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm
 Eluent A Acetonitrile
 Eluent B 0.1 % Phosphoric acid (Water)
 Gradient

time	%A	%B
0min	0	100
22.5min	90	10
25min	90	10

Flow 1.0 ml min-1
 Detector UV-220nm
 Injection-Volume 5 µl
 Sample 2.0 mg ml-1 (Acetonitrile)



Detector A - 1 (280nm)

Retention Time	Height	Area	Area Percent	
11,633	3128	21453	0,16	
11,833	200	745	0,01	
11,983	603	5681	0,04	
12,317	2089	25761	0,19	
12,633	81404	599731	4,50	
12,842	77852	12339308	92,57	<- Sum of Tylosin
14,233	8018	63505	0,48	A, B, C and D
14,383	10541	89103	0,67	
14,658	4132	39795	0,30	
14,983	4796	56785	0,43	
15,208	1512	12057	0,09	
15,442	5937	47622	0,36	
15,692	788	4976	0,04	
15,817	1426	9784	0,07	
16,108	130	1213	0,01	
16,425	271	3610	0,03	
17,083	287	3411	0,03	
17,325	180	1025	0,01	
19,350	191	1059	0,01	
20,450	238	1561	0,01	
20,867	254	1824	0,01	
Totals	203977	13330009	100,00	

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
3.0	683379	804435	Format update	04 Aug 2021

