

Page 1/2 Version 2

672955 Lot: 818525

**Erythromycin** 

1. General Information

Formula C37H67NO13 Expiry Date 01 May 2028

Mol. Weight 733.93 g/mol Store at 20°C (in the dark)

CAS-No. 114-07-8

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 98.11 % (g/g) Expanded Uncertainty 0.41 % (g/g)

Assay Purity (HPLC) 99.61 % (g/g) Uncertainty 0.20 % (g/g)

Water 1.51 % (g/g)
Sum of compounds A, B and C

Erythromycin A: 92.68% Erythromycin B: 6.34% Erythromycin C: 0.71%

Certified on 28 Apr 2023

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.

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).





Article 672955 Lot-No. 818525

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

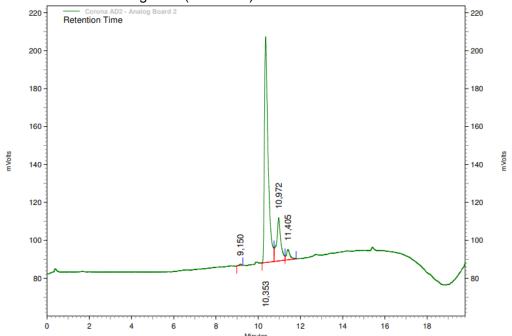
Gradient time %A %B 0min 0 100

15min 95 5 20min 95 5

Flow 0.7 ml min-1

Detector CAD Injection-Volume 1 µI

Sample 1.0 mg ml-1 (Methanol)



Corona AD2 -Analog Board 2 Results

| Retention Time | Height | Area    | Area Percent |
|----------------|--------|---------|--------------|
| 9,150          | 705    | 5130    | 0,283        |
| 10,353         | 119034 | 1430997 | 78,997       |
| 10,972         | 22828  | 312089  | 17,229       |
| 11,405         | 5468   | 63231   | 3,491        |

| D 1 1 DM 10 050 | 1 1 2 1 1 |         |         |
|-----------------|-----------|---------|---------|
|                 | 148035    | 1811447 | 100,000 |
| Totals          |           |         |         |

Peak at RT 10,353min is Erythromycin A Peak at RT 10,972min is Erythromycin C Peak at RT 11,405min is Erythromycin B

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 672955  | 818525 | Initial Version   | 28 Apr 2023 |
| 2       | 672955  | 818525 | Text update       | 08 Jun 2023 |



Page 1/2 Version 1

672975 Lot: 826330

**Sulfamerazine** 

1. General Information

Formula C11H12N4O2S Expiry Date 01 Jul 2030

Mol. Weight 264.30 g/mol Store at 20°C (in the dark)

CAS-No. 127-79-7

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.90 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.90 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 02 Jul 2024

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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).



## **HPLC-Method**

Article 672975 Lot-No. 826330

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

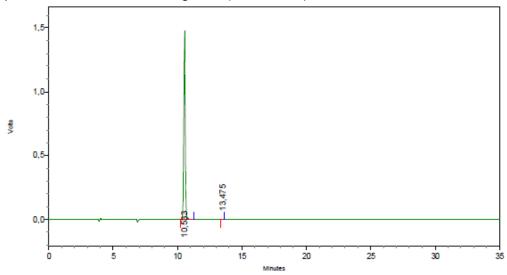
 0min
 0
 100

 22.5min
 90
 10

22.5min 90 10 25min 90 10

Flow 1.0 ml min-1
Detector UV-220nm
Injection-Volume 10 µl

Sample 0.3 mg ml-1 (Acetonitrile)



#### Detector A - 1 (220nm)

| Retention Time | Height  | Area     | Area Percent |
|----------------|---------|----------|--------------|
| 10,533         | 1479537 | 10362270 | 99,90        |
| 13.475         | 1401    | 9982     | 0,10         |

| Totals |         |          |        |
|--------|---------|----------|--------|
|        | 1480938 | 10372252 | 100,00 |

| ſ | Version | Article | Lot    | Reason for Change | Date        |
|---|---------|---------|--------|-------------------|-------------|
| Ī | 1       | 672975  | 826330 | Initial Version   | 02 Jul 2024 |



Page 1/2 Version 1

674582 Lot: 826910

**Chloramphenicol** 

1. General Information

Formula C11H12Cl2N2O5 Expiry Date 01 Aug 2029

Mol. Weight 323.13 g/mol Store at 4°C (in the dark)

CAS-No. 56-75-7

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.89 % (g/g) Expanded Uncertainty 0.40 % (g/g)

Assay Purity (HPLC) 99.89 % (g/g) Uncertainty 0.20 % (g/g)

Certified on 01 Aug 2024

by Jacqueline Seidel RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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).



Article 674582 Lot-No. 826910

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

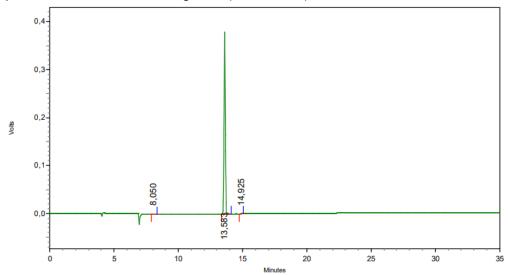
 22.5min
 90
 10

 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 |
|----------------|--------|---------|--------------|
| 8,050          | 102    | 711     | 0,03         |
| 13,583         | 379821 | 2451592 | 99,96        |
| 14,925         | 67     | 372     | 0,02         |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 379990 | 2452675 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 674582  | 826910 | Initial Version   | 01 Aug 2024 |



Page 1/2 Version 1

674760 Lot: 820073

**Thiamphenicol** 

1. General Information

Formula C12H15Cl2NO5S Expiry Date 01 Jul 2028

Mol. Weight 356.22 g/mol Store at 4°C (in the dark)

CAS-No. 15318-45-3

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.24 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.24 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 13 Jul 2023

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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** 

Article 674760 Lot-No. 820073

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

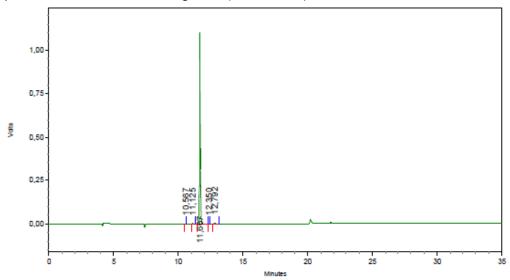
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1
Detector UV-220nm

Injection-Volume 10 µl

Sample 0.3 mg ml-1 (Acetonitrile)



#### Detector A - 1 (220nm)

| Detector II - I (220IIII) |         |         |              |
|---------------------------|---------|---------|--------------|
| Retention Time            | Height  | Area    | Area Percent |
| 10,567                    | 112     | 514     | 0,01         |
| 11,125                    | 2911    | 15166   | 0,25         |
| 11,667                    | 1103809 | 5903257 | 99,24        |
| 12,350                    | 199     | 942     | 0,02         |
| 12,792                    | 5215    | 28439   | 0,48         |
|                           |         |         |              |

| Totals |         |         |        |
|--------|---------|---------|--------|
|        | 1112246 | 5948318 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 674760  | 820073 | Initial Version   | 13 Jul 2023 |



Page 1/2 Version 1

674874 Lot: 825440 **Difloxacin hydrochloride** 

1. General Information

Formula C21H20CIF2N3O3 Expiry Date 01 Jun 2028

Mol. Weight 435.85 g/mol Store at 4°C (in the dark)

CAS-No. 91296-86-5

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.26 % (g/g) Expanded Uncertainty 0.36 % (g/g)

Assay Purity (HPLC) 99.26 % (g/g) Uncertainty 0.18 % (g/g)

Certified on 15 May 2024

an, Knyking

by YingYing Gao RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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).





Article 674874 Lot-No. 825440

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

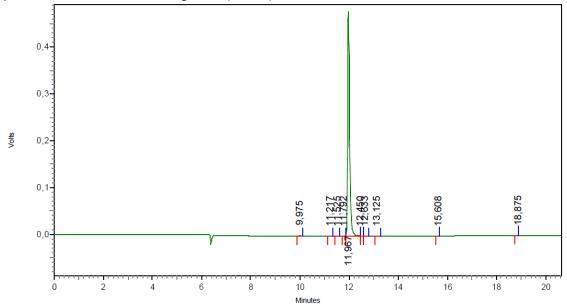
 22.5min
 90
 10

 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 |
|----------------|--------|---------|--------------|
| 9,975          | 1632   | 8338    | 0,27         |
| 11,217         | 254    | 1269    | 0,04         |
| 11,525         | 206    | 1103    | 0,04         |
| 11,792         | 669    | 3011    | 0,10         |
| 11,967         | 479430 | 3070787 | 99,29        |
| 12,450         | 819    | 3825    | 0,12         |
| 12,633         | 491    | 3524    | 0,11         |
| 13,125         | 88     | 508     | 0,02         |
| 15,608         | 41     | 192     | 0,01         |
| 18,875         | 20     | 329     | 0,01         |

|   | Totals |        |         |        |
|---|--------|--------|---------|--------|
|   |        | 483650 | 3092886 | 100,00 |
| - |        |        |         |        |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 674874  | 825440 | Initial Version   | 15 May 2024 |



Page 1/2 Version 2

674894 Lot: 812328

**Marbofloxacin** 

1. General Information

Formula C17H19FN4O4 Expiry Date 01 Sep 2027

Mol. Weight 362.36 g/mol Store at 20°C (in the dark)

CAS-No. 115550-35-1

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.99 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.99 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 19 Aug 2022

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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** 

## **HPLC-Method**

Article 674894 Lot-No. 812328

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

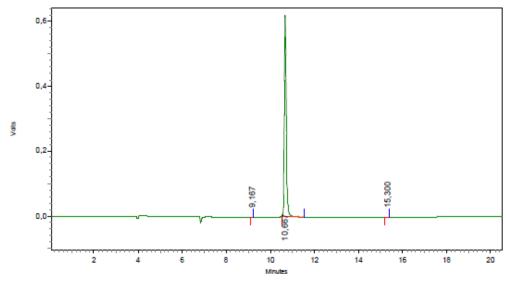
 22.5min
 90
 10

 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 |
|----------------|--------|---------|--------------|
| 9,167          | 51     | 214     | 0,01         |
| 10,667         | 620536 | 3834894 | 99,99        |
| 15,300         | 35     | 225     | 0,01         |

| Totals |         |        |
|--------|---------|--------|
| 620622 | 3835333 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 674894  | 812328 | Initial Version   | 19 Aug 2022 |
| 2       | 674894  | 812328 | Text update       | 08 Jun 2023 |



Page 1/2 Version 1

674906 Lot: 826236

**Flubendazole** 

1. General Information

Formula C16H12FN3O3 Expiry Date 01 Jul 2029

Mol. Weight 313.28 g/mol Store at 20°C (in the dark) CAS-No. 31430-15-6

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 98.18 % (g/g) Expanded Uncertainty 0.52 % (g/g)

Assay Purity (HPLC) 98.18 % (g/g) Uncertainty 0.26 % (g/g)

Certified on 25 Jun 2024

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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).





Article 674906 Lot-No. 826236

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

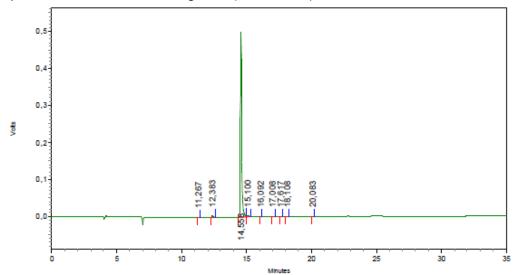
 22.5min
 90
 10

 30min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5µl

Sample 0.1 mg ml-1 (Acetonitrile)



| Detector A | Λ 1 | (220mm) |
|------------|-----|---------|
| Detector / | - I | 1220HHI |

| Detector A - 1 (220nm) |        |         |              |
|------------------------|--------|---------|--------------|
| Retention Time         | Height | Area    | Area Percent |
| 11,267                 | 151    | 831     | 0,02         |
| 12,383                 | 3642   | 22725   | 0,63         |
| 14,558                 | 499656 | 3542182 | 98,31        |
| 15,100                 | 3214   | 24602   | 0,68         |
| 16,092                 | 475    | 2430    | 0,07         |
| 17,008                 | 160    | 1068    | 0,03         |
| 17,617                 | 318    | 2702    | 0,07         |
| 18,108                 | 551    | 3555    | 0,10         |
| 20,083                 | 541    | 3133    | 0,09         |

| Totals |         |        |
|--------|---------|--------|
| 508708 | 3603228 | 100,00 |

| Example y anionatogram of given motion. |         |         |        |                   |             |
|---|---------|---------|--------|-------------------|-------------|
|   | Version | Article | Lot    | Reason for Change | Date        |
|   | 1       | 674906  | 826236 | Initial Version   | 25 Jun 2024 |



Page 1/2 Version 1

675355 Lot: 821568

**Sulfadimethoxine** 

1. General Information

Formula C12H14N4O4S Expiry Date 01 Nov 2029

Mol. Weight 310.33 g/mol Store at 4°C (in the dark)

CAS-No. 122-11-2

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.93 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.93 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 16 Oct 2023

by Corinna Gröst RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).



10

## **HPLC-Method**

Flow

Detector

Article 675355 Lot-No. 821568

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

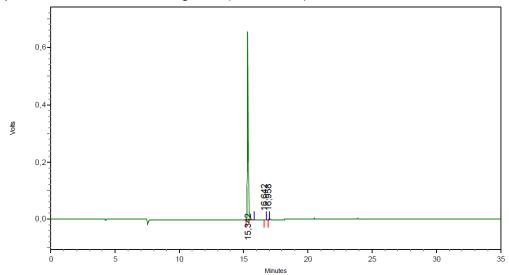
 0min
 0
 100

 22.5min
 90
 10

25min 90 1.0 ml min-1 UV-220nm

Injection-Volume 5 µl

Sample 0.3 mg ml-1 (Acetonitrile)



Detector A - 1 (220nm)

| Retention Time | Height | Area    | Area Percent |
|----------------|--------|---------|--------------|
| 15,342         | 656432 | 3680936 | 99,93        |
| 16,642         | 227    | 1087    | 0,03         |
| 16,958         | 360    | 1598    | 0,04         |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 657019 | 3683621 | 100,00 |

| Exemplary ememalogram of given method. |         |         |        |                   |             |
|--|---------|---------|--------|-------------------|-------------|
|  | Version | Article | Lot    | Reason for Change | Date        |
|  | 1       | 675355  | 821568 | Initial Version   | 16 Oct 2023 |



Page 1/2 Version 2

675368 Lot: 811584

**Sulfadoxine** 

1. General Information

Formula C12H14N4O4S Expiry Date 01 Aug 2028

Mol. Weight 310.34 g/mol Store at 4°C (in the dark)

CAS-No. 2447-57-6

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.07 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.07 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 08 Aug 2022

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).





Article 675368 Lot-No. 811584

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

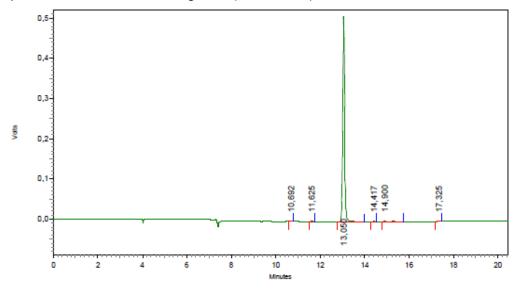
 22.5min
 90
 10

 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 |
|----------------|--------|---------|--------------|
| 10,692         | 205    | 1248    | 0,04         |
| 11,625         | 684    | 3530    | 0,11         |
| 13,050         | 509650 | 3132563 | 99,06        |
| 14,417         | 714    | 3983    | 0,13         |
| 14,900         | 1567   | 19488   | 0,62         |
| 17,325         | 249    | 1459    | 0,05         |

| Totals |         |        |
|--------|---------|--------|
| 513069 | 3162271 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 675368  | 811584 | Initial Version   | 08 Aug 2022 |
| 2       | 675368  | 811584 | Text update       | 08 Jun 2023 |



Page 1/2 Version 1

675370 Lot: 822400 **Sulfamethoxypyridazine** 

1. General Information

Formula C11H12N4O3S Expiry Date 01 Dec 2028

Mol. Weight 280.30 g/mol Store at 4°C (in the dark)

CAS-No. 80-35-3

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 98.76 % (g/g) Expanded Uncertainty 0.36 % (g/g)

Assay Purity (HPLC) 98.76 % (g/g) Uncertainty 0.18 % (g/g)

Certified on 30 Nov 2023

by Corinna Gröst RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).





Article 675370 Lot-No. 822400

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

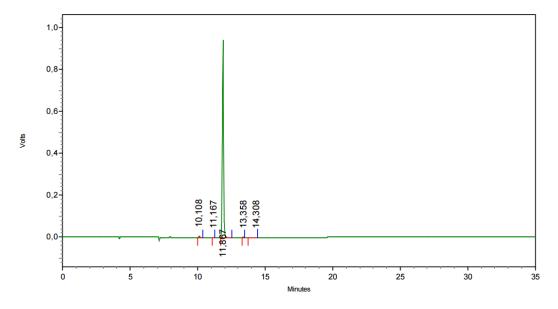
 22.5min
 90
 10

 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 |
|----------------|--------|---------|--------------|
| 10,108         | 7035   | 40018   | 0,76         |
| 11,167         | 166    | 835     | 0,02         |
| 11,867         | 942234 | 5224035 | 98,80        |
| 13,358         | 2476   | 13073   | 0,25         |
| 14,308         | 1155   | 9302    | 0,18         |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 953066 | 5287263 | 100,00 |

| - | Version | Article | Lot    | Reason for Change | Date        |
|---|---------|---------|--------|-------------------|-------------|
| Γ | 1       | 675370  | 822400 | Initial Version   | 30 Nov 2023 |



Page 1/2 Version 1

675451 Lot: 827959
Penicillin G potassium salt

1. General Information

Formula C16H17KN2O4S Expiry Date 01 Oct 2028

Mol. Weight 372.48 g/mol Store at 4°C (in the dark)

CAS-No. 113-98-4

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.13 % (g/g) Expanded Uncertainty 0.50 % (g/g)

Assay Purity (HPLC) 99.13 % (g/g) Uncertainty 0.23 % (g/g)

Water <0.1 % (g/g)

contains 4.22% potassium

Certified on 01 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).



## **HPLC-Method**

Article 675451 Lot-No. 827959

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

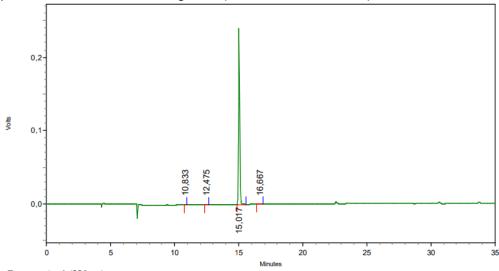
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5 µl

Sample 0.3 mg ml-1 (Acetonitrile/Water 1:1)



| Detector A - 1 (220nm) | THE MASS |         |              |
|------------------------|----------|---------|--------------|
| Retention Time         | Height   | Area    | Area Percent |
| 10,833                 | 547      | 3027    | 0,22         |
| 12,475                 | 705      | 4744    | 0,34         |
| 15,017                 | 240440   | 1379492 | 99,23        |
| 16,667                 | 157      | 2898    | 0,21         |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 241849 | 1390161 | 100,00 |

|   | Version | Article | Lot    | Reason for Change | Date        |
|---|---------|---------|--------|-------------------|-------------|
| Γ | 1       | 675451  | 827959 | Initial Version   | 01 Oct 2024 |



Page 1/2 Version 2

675529 Lot: 806989

**Sulfanitran** 

1. General Information

Formula C14H13N3O5S Expiry Date 01 Jan 2027

Mol. Weight 335.34 g/mol Store at 4°C (in the dark)

CAS-No. 122-16-7

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 97.95 % (g/g) Expanded Uncertainty 0.36 % (g/g)

Assay Purity (HPLC) 97.95 % (g/g) Uncertainty 0.18 % (g/g)

Certified on 15 Dec 2021

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).





Article 675529 Lot-No. 806989

Column L=250mm, ID=4.6mm; Luna-Omega Polar C18, 100A, 5µm

Eluent A Acetonitrile

Eluent B 0.1 % Phosphoric acid (Water)

 Gradient
 time
 %A
 %B

 0min
 0
 100

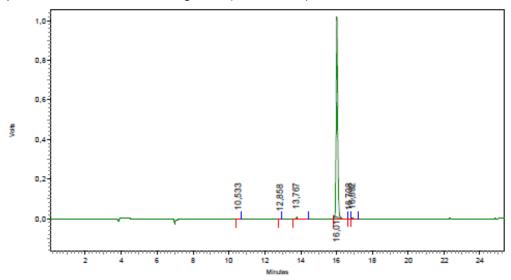
 22.5min
 90
 10

 30min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 10 µl

Sample 0.3 mg ml-1 (Acetonitrile)



| Detector A - 1 (220nm)<br>Retention Time | Height  | Area    | Area Percent  |
|--|---------|---------|---------------|
| Retention Time                           | neight  | Area    | Alea Pelcelli |
| 10,533                                   | 2634    | 14544   | 0,25          |
| 12,858                                   | 575     | 3103    | 0,05          |
| 13,767                                   | 8299    | 70870   | 1,22          |
| 16,017                                   | 1019795 | 5686935 | 97,99         |
| 16,708                                   | 485     | 3821    | 0,07          |
| 16,892                                   | 4014    | 24513   | 0,42          |

| 1 otals |         |         |        |
|---------|---------|---------|--------|
|         | 1035802 | 5803786 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 675529  | 806989 | Initial Version   | 15 Dec 2021 |
| 2       | 675529  | 806989 | Text update       | 08 Jun 2023 |



Page 1/3 Version 1

676035 Lot: 825031 Sarafloxacin hydrochloride

1. General Information

Formula C20H18CIF2N3O3 Expiry Date 01 May 2029

Mol. Weight 421.83 g/mol Store at 4°C (in the dark)

CAS-No. 91296-87-6

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 95.82 % (g/g) Expanded Uncertainty 0.52 % (g/g)

Assay Purity (HPLC) 96.73 % (g/g) Uncertainty 0.25 % (g/g)

Water 0.94 % (g/g)

Certified on 29 Apr 2024

by Corinna Gröst 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 ± 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).





Article 676035 Lot-No. 825031

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

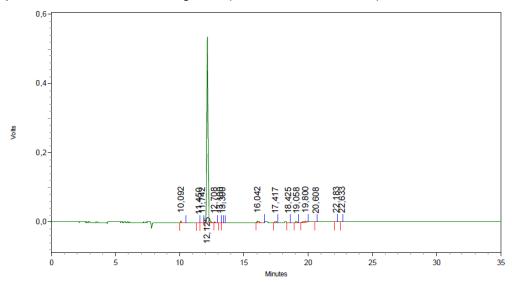
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5 µl

Sample 0.3 mg ml-1 (Acetonitrile/Water, 1/1)



| Detector A - 1 (220nm) |        |         |              |
|------------------------|--------|---------|--------------|
| Retention Time         | Height | Area    | Area Percent |
| 10,092                 | 4695   | 25097   | 0,73         |
| 11,450                 | 249    | 1264    | 0,04         |
| 11,742                 | 932    | 5281    | 0,15         |
| 12,125                 | 537016 | 3310162 | 96,86        |
| 12,708                 | 874    | 5108    | 0,15         |
| 13,100                 | 761    | 3669    | 0,11         |
| 13,300                 | 144    | 889     | 0,03         |
| 16,042                 | 3093   | 23863   | 0,70         |
| 17,417                 | 591    | 5484    | 0,16         |
| 18,425                 | 166    | 1153    | 0,03         |
| 19,058                 | 358    | 2816    | 0,08         |
| 19,800                 | 2533   | 28522   | 0,83         |
| 20,608                 | 129    | 667     | 0,02         |
| 22,183                 | 321    | 2112    | 0,06         |
| 22,633                 | 258    | 1435    | 0,04         |
| Totals                 |        |         |              |
|                        | 552120 | 3417522 | 100,00       |



Page 3/3 Version 1

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 676035  | 825031 | Initial Version   | 29 Apr 2024 |



Page 1/2 Version 1

676306 Lot: 827606 Penicillin V potassium salt

1. General Information

Formula C16H17KN2O5S Expiry Date 01 Sep 2026

Mol. Weight 388.48 g/mol Store at 4°C (in the dark)

CAS-No. 132-98-9

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 98.80 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 98.91 % (g/g) Uncertainty 0.17 % (g/g)

Water 0.11 % (g/g)

Potassium determination: 5.91%

Certified on 09 Sep 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).



## **HPLC-Method**

Article 676306 Lot-No. 827606

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

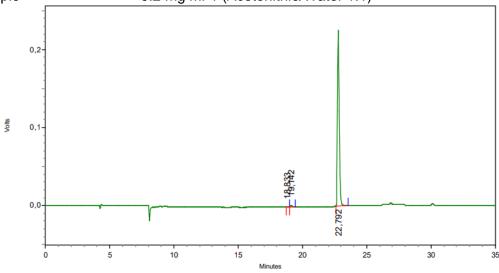
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5 µl

Sample 0.2 mg ml-1 (Acetonitrile/Water 1:1)



| Detector A - 1 (220nm) |        |         |              |
|------------------------|--------|---------|--------------|
| Retention Time         | Height | Area    | Area Percent |
| 18,833                 | 122    | 896     | 0,04         |
| 19,142                 | 2367   | 22249   | 1,03         |
| 22,792                 | 226033 | 2133239 | 98,93        |
|                        |        |         |              |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 228522 | 2156384 | 100,00 |

|         |         |        |                   | 1           |
|---------|---------|--------|-------------------|-------------|
| Version | Article | Lot    | Reason for Change | Date        |
| 1       | 676306  | 827606 | Initial Version   | 09 Sep 2024 |



Page 1/2 Version 1

676361 Lot: 824760

Cefquinome sulfate

## 1. General Information

Formula C23H26N6O9S3 Expiry Date 01 May 2029

Mol. Weight 626.68 g/mol Store at 4°C (in the dark)

CAS-No. 118443-89-3

## 2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 94.93 % (g/g) Expanded Uncertainty 0.57 % (g/g)

Assay Purity (HPLC) 97.79 % (g/g) Uncertainty 0.18 % (g/g) Water 2.22 % (g/g)

Inorganic Impurities 0.70 % (g/g) Uncertainty 0.10 % (g/g)

#### Certified on 15 Apr 2024

by Corinna Gröst 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 ± 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).





Article 676361 Lot-No. 824760

Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm

Eluent A Acetonitrile

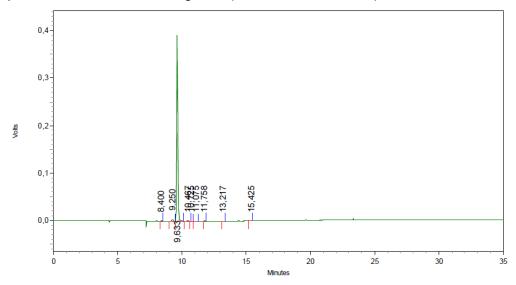
Eluent B 0.1 % Phosphoric acid (Water)

Gradient %A %В time 0 100 0min 22.5min 90 10 25min 90 10

Flow 1.0 ml min-1 UV-220nm Detector

Injection-Volume 5 µl

Sample 0.3 mg ml-1 (Acetonitrile/Water 1/1)



| Detector A - 1 | (220nm) |
|----------------|---------|
|----------------|---------|

| Defeation Time | TT-1-1-4 | A       | A D          |
|----------------|----------|---------|--------------|
| Retention Time | Height   | Area    | Area Percent |
| 8,400          | 1146     | 6275    | 0,28         |
| 9,250          | 3448     | 28476   | 1,28         |
| 9,633          | 392284   | 2180716 | 97,67        |
| 10,467         | 886      | 6491    | 0,29         |
| 10,725         | 239      | 1288    | 0,06         |
| 11,075         | 312      | 3619    | 0,16         |
| 11,758         | 582      | 3791    | 0,17         |
| 13,217         | 216      | 1264    | 0,06         |
| 15,425         | 69       | 818     | 0,04         |
| ,              |          |         |              |
| Totals         |          |         |              |

399182

Exemplary chromatogram of given method.

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 676361  | 824760 | Initial Version   | 15 Apr 2024 |

2232738



Page 1/2 Version 2

676444 Lot: 806156 Dimetridazole-2-hydroxy

1. General Information

Formula C5H7N3O3 Expiry Date 01 Nov 2026

Mol. Weight 157.13 g/mol Store at 4°C (in the dark)

CAS-No. 936-05-0

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.63 % (g/g) Expanded Uncertainty 0.36 % (g/g)

Assay Purity (HPLC) 99.63 % (g/g) Uncertainty 0.18 % (g/g)

Certified on 29 Oct 2021

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).





Article 676444 Lot-No. 806156

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

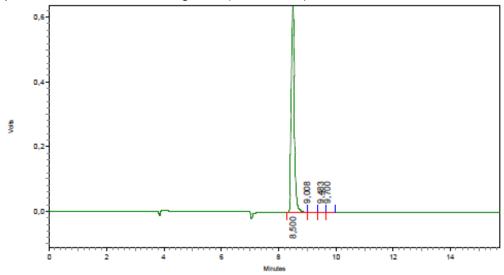
 0min
 0
 100

 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1
Detector UV-220nm
Injection-Volume 10 µl

Sample 0.3 mg ml-1 (Acetonitrile)



#### Detector A - 1 (220nm)

| Delector A - I (220mil) |        |         |              |
|-------------------------|--------|---------|--------------|
| Retention Time          | Height | Area    | Area Percent |
| 8,500                   | 637327 | 4685168 | 99,60        |
| 9,008                   | 722    | 7235    | 0,15         |
| 9,483                   | 1137   | 9583    | 0,20         |
| 9,700                   | 229    | 1902    | 0,04         |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 639415 | 4703888 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 676444  | 806156 | Initial Version   | 29 Oct 2021 |
| 2       | 676444  | 806156 | Text update       | 08 Jun 2023 |



Page 1/2 Version 2

676822 Lot: 816552

# 2-Aminoflubendazole

## 1. General Information

Formula C14H10FN3O Expiry Date 01 Feb 2028

Mol. Weight 255.25 g/mol Store at 4°C (in the dark)

CAS-No. 82050-13-3

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 98.72 % (g/g) Expanded Uncertainty 0.44 % (g/g)

Assay Purity (HPLC) 98.72 % (g/g) Uncertainty 0.22 % (g/g)

Certified on 13 Feb 2023

by Jacqueline Seidel RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).





Article 676822 Lot-No. 816552

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

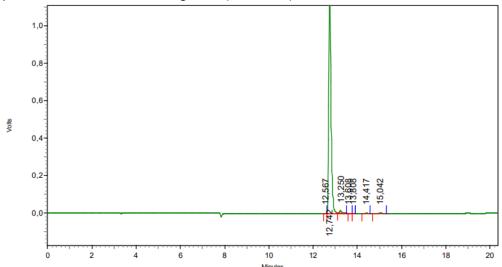
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5 µl

Sample 0.3 mg ml-1 (Methanol)



| Detector A - | 1.(220nm) |
|--------------|-----------|
|              |           |

| Detector II I (220min) |         |         |              |
|------------------------|---------|---------|--------------|
| Retention Time         | Height  | Area    | Area Percent |
| 12,567                 | 1333    | 6592    | 0,08         |
| 12,742                 | 1141361 | 8523467 | 98,62        |
| 13,250                 | 11447   | 83112   | 0,96         |
| 13,608                 | 130     | 771     | 0,01         |
| 13,808                 | 96      | 449     | 0,01         |
| 14,417                 | 1481    | 9212    | 0,11         |
| 15,042                 | 2172    | 19216   | 0,22         |
|                        |         |         |              |

| Totals | 1158020 | 8642819 | 100.00 |
|--------|---------|---------|--------|
|        | 1130020 | 0042017 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 676822  | 816552 | Initial Version   | 13 Feb 2023 |
| 2       | 676822  | 816552 | Text update       | 08 Jun 2023 |



Page 1/2 Version 1

676824 Lot: 825658

**Febantel** 

1. General Information

Formula C20H22N4O6S Expiry Date 01 Jun 2029

Mol. Weight 446.48 g/mol Store at 4°C (in the dark)

CAS-No. 58306-30-2

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.87 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.87 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 27 May 2024

by Corinna Gröst RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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 ± 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).





Article 676824 Lot-No. 825658

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

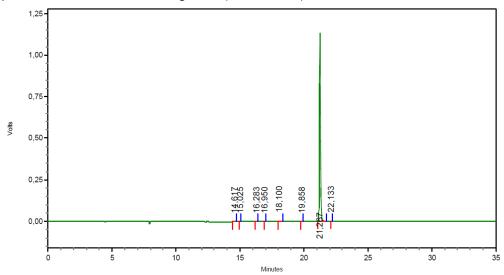
 22.5min
 90
 10

 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 |
|----------------|---------|---------|--------------|
| 14,617         | 66      | 755     | 0,01         |
| 15,025         | 123     | 517     | 0,01         |
| 16,283         | 83      | 559     | 0,01         |
| 16,950         | 53      | 190     | 0,00         |
| 18,100         | 887     | 5248    | 0,08         |
| 19,858         | 179     | 945     | 0,01         |
| 21,267         | 1132321 | 6850819 | 99,87        |
| 22,133         | 172     | 784     | 0,01         |

| Totals |         |         |        |
|--------|---------|---------|--------|
|        | 1133884 | 6859817 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 676824  | 825658 | Initial Version   | 27 May 2024 |



Page 1/2 Version 2

676878 Lot: 818700

**Doramectin** 

1. General Information

Formula C50H74O14 Expiry Date 01 May 2028

Mol. Weight 899.11 g/mol Store at -20°C (in the dark)

CAS-No. 117704-25-3

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 96.00 % (g/g) Expanded Uncertainty 0.40 % (g/g)

Assay Purity (HPLC) 96.00 % (g/g) Uncertainty 0.20 % (g/g)

Certified on 08 May 2023

by Jacqueline Seidel RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).





Article 676878 Lot-No. 818700

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

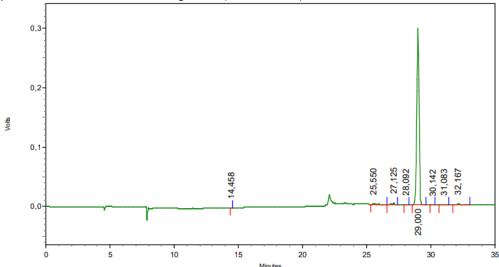
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5 μl

Sample 1.0 mg ml-1 (Acetonitrile)



| Detector A - 1 (220nm) |        |         |              |  |  |  |
|------------------------|--------|---------|--------------|--|--|--|
| Retention Time         | Height | Area    | Area Percent |  |  |  |
| 14,458                 | 130    | 574     | 0,02         |  |  |  |
| 25,550                 | 819    | 30892   | 0,84         |  |  |  |
| 27,125                 | 3432   | 54669   | 1,49         |  |  |  |
| 28,092                 | 599    | 5754    | 0,16         |  |  |  |
| 29,000                 | 297652 | 3529424 | 96,07        |  |  |  |
| 30,142                 | 211    | 2709    | 0,07         |  |  |  |
| 31,083                 | 649    | 13551   | 0,37         |  |  |  |
| 32,167                 | 1811   | 36294   | 0,99         |  |  |  |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 305303 | 3673867 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 676878  | 818700 | Initial Version   | 08 May 2023 |
| 2       | 676878  | 818700 | Text update       | 08 Jun 2023 |



Page 1/2 Version 1

677092 Lot: 827180 **Fenbendazole-sulfone** 

1. General Information

Formula C15H13N3O4S Expiry Date 01 Sep 2027

Mol. Weight 331.35 g/mol Store at 20°C (in the dark)

CAS-No. 54029-20-8

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.80 % (g/g) Expanded Uncertainty 0.41 % (g/g)

 Assay Purity (HPLC)
 99.90 % (g/g)
 Uncertainty
 0.18 % (g/g)

 Residual Solvents
 0.10 % (g/g)
 Uncertainty
 0.10 % (g/g)

Certified on 15 Aug 2024

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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).



#### **HPLC-Method**

Article 677092 Lot-No. 827180

Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm

Eluent A Acetonitrile

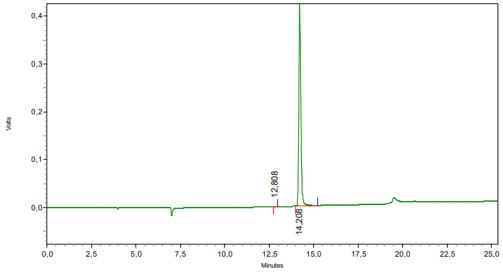
Eluent B 0.1 % Phosphoric acid (Water)

Gradient %A %В time 0 100 0min 22.5min 90 10

25min 90 10

Flow 1.0 ml min-1 UV-220nm Detector Injection-Volume 5 µl

Sample 0.1 mg ml-1 (Acetonitrile/Water 1/1)



Detector A - 1 (220nm)

| Retention Time | Height | Area    | Area Percent |
|----------------|--------|---------|--------------|
| 12,808         | 324    | 2428    | 0,08         |
| 14,208         | 427579 | 3103013 | 99,92        |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 427903 | 3105441 | 100,00 |

|  | Version | Article | Lot    | Reason for Change | Date        |
|--|---------|---------|--------|-------------------|-------------|
|  | 1       | 677092  | 827180 | Initial Version   | 15 Aug 2024 |



Page 1/3 Version 2

677425 Lot: 819010

**Tilmicosin** 

1. General Information

Formula C46H80N2O13 Expiry Date 01 Jun 2028

Mol. Weight 869.13g/mol Store at 20°C (in the dark)

CAS-No. 108050-54-0

2. Batch Analysis

Identity confirmed

Overall Purity 92.80 % (g/g) Expanded Uncertainty 0.50 % (g/g)

Assay Purity (HPLC) 92.80 % (g/g) Uncertainty 0.25 % (g/g)

Certified on 22 May 2023

an, Knyking

by YingYing Gao RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).







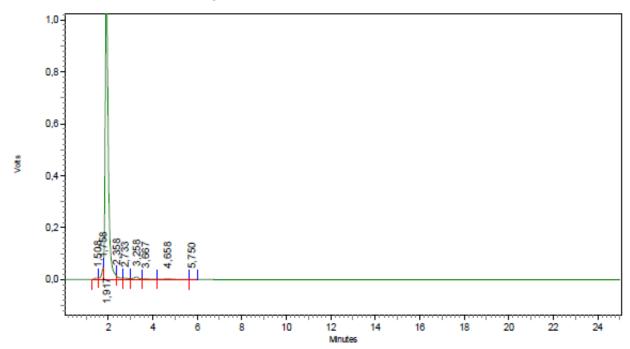
Article 677425 Lot-No. 819010

Column L=250mm, ID=4.6mm; Reprosil-PUR C-18 AQ, 10µm Eluent Acetonitrile/0.1% Phosphoric acid (Water) 40/50

Flow 1.5 ml min-1
Detector UV-254nm

Injection-Volume 20µl

Sample 3.0 mg ml-1 (Eluent)



#### Detector A - 1 (254nm)

| Retention Time | Height  | Area     | Area Percent |
|----------------|---------|----------|--------------|
| 1,508          | 6084    | 73773    | 0,63         |
| 1,758          | 41809   | 216017   | 1,83         |
| 1,917          | 1164726 | 10926985 | 92,80        |
| 2,358          | 15345   | 126365   | 1,07         |
| 2,733          | 5214    | 90897    | 0,77         |
| 3,258          | 10292   | 178394   | 1,52         |
| 3,667          | 2807    | 68144    | 0,58         |
| 4,658          | 2477    | 91255    | 0,78         |
| 5,750          | 159     | 2436     | 0,02         |
| Totals         |         |          |              |

Exemplary chromatogram of given method.

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 677425  | 819010 | Initial Version   | 22 May 2023 |

11774266

1248913



Page 3/3 Version 2

2 677425 819010 Text update 08 Jun 2023



Page 1/2 Version 1

677666 Lot: 826347

Benzo[a]pyrene

1. General Information

Formula C20H12 Expiry Date 01 Jul 2029

Mol. Weight 252.31 g/mol Store at 20°C (in the dark)

CAS-No. 50-32-8

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.70 % (g/g) Expanded Uncertainty 0.38 % (g/g)

Assay Purity (HPLC) 99.70 % (g/g) Uncertainty 0.19 % (g/g)

Certified on 02 Jul 2024

by Philipp Schwarzenberger RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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. 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).





Article 677666 Lot-No. 826347

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

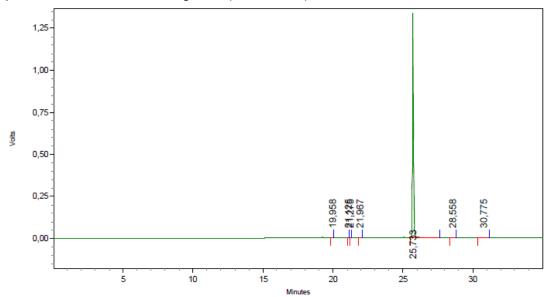
 22.5min
 90
 10

 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)

| Height  | Area                         | Area Percent  |
|---------|------------------------------|---|
|         |                              | 0,08  |
| 93      |                              | 0,01  |
| 153     | 617                          | 0,01  |
| 997     | 5394                         | 0,07  |
| 1334574 | 8065803                      | 99,64   |
| 953     | 7696                         | 0,10  |
| 369     | 8600                         | 0,11  |
|         | 153<br>997<br>1334574<br>953 | 1167 6425<br>93 434<br>153 617<br>997 5394<br>1334574 8065803<br>953 7696 |

| Totals |         |         |        |
|--------|---------|---------|--------|
|        | 1338306 | 8094969 | 100,00 |

|   | Version | Article | Lot    | Reason for Change | Date        |
|---|---------|---------|--------|-------------------|-------------|
| ſ | 1       | 677666  | 826347 | Initial Version   | 02 Jul 2024 |



Page 1/2 Version 1

679188 Lot: 823610

**Brombuterol** 

1. General Information

Formula C12H18Br2N2O Expiry Date 01 Feb 2027

Mol. Weight 366.09 g/mol Store at 4°C (in the dark)

CAS-No. 41937-02-4

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.87 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.87 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 05 Feb 2024

by Corinna Gröst RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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. 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).



Article 679188 Lot-No. 823610

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

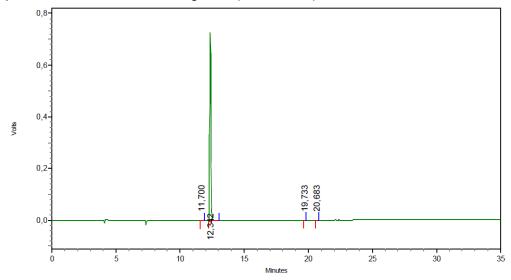
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 10 µl

Sample 0.12 mg ml-1 (Acetonitrile)



#### Detector A - 1 (220nm)

| Retention Time | Height | Area    | Area Percent |
|----------------|--------|---------|--------------|
| 11,700         | 389    | 3100    | 0,06         |
| 12,342         | 727449 | 4787145 | 99,87        |
| 19,733         | 381    | 1689    | 0,04         |
| 20,683         | 219    | 1299    | 0,03         |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 728438 | 4793233 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 679188  | 823610 | Initial Version   | 05 Feb 2024 |



Page 1/2 Version 1

679413 Lot: 824260

Closantel

1. General Information

Formula C22H14Cl2l2N2O2 Expiry Date 01 Mar 2027

Mol. Weight 663.07 g/mol Store at 20°C (in the dark)

CAS-No. 57808-65-8

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.49 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.49 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 13 Mar 2024

by Philipp Schwarzenberger RM Release

hwarzenbege-

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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).



#### **HPLC-Method**

Article 679413 Lot-No. 824260

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

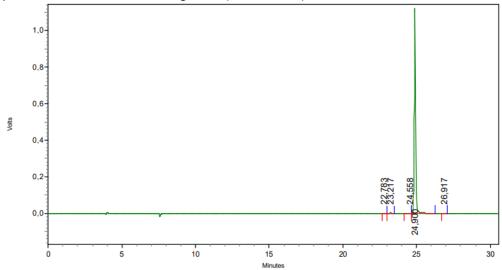
 22.5min
 90
 10

 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)

| Reter | ntion Time | Height  | Area    | Area Percent |
|-------|------------|---------|---------|--------------|
|       | 22,783     | 833     | 5374    | 0,07         |
|       | 23,217     | 2430    | 23204   | 0,29         |
|       | 24,558     | 584     | 8198    | 0,10         |
|       | 24,900     | 1122406 | 7855393 | 99,50        |
|       | 26,917     | 290     | 2788    | 0,04         |
|       |            |         |         |              |

| Totals |         |         |        |
|--------|---------|---------|--------|
|        | 1126543 | 7894957 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 679413  | 824260 | Initial Version   | 13 Mar 2024 |



Page 1/2 Version 1

680142 Lot: 829660

13C6-Thiabendazole

1. General Information

Formula (13C)6C4H7N3S Expiry Date 01 Jan 2027

Mol. Weight 207.30 g/mol Store at 4°C (in the dark)

CAS-No. 2140327-29-1

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.98 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.98 % (g/g) Uncertainty 0.17 % (g/g)

Atom% 99.3 D

Con, Knyking

Certified on 08 Jan 2025

by YingYing Gao RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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).



#### **HPLC-Method**

Article 680142 Lot-No. 829660

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

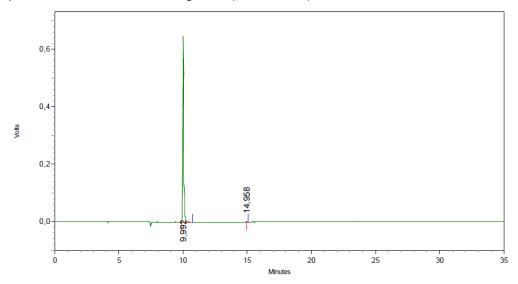
 22.5min
 90
 10

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 |
|----------------|--------|---------|--------------|
| 9,992          | 648170 | 3985446 | 99,97        |
| 14,958         | 399    | 1327    | 0,03         |
|                |        |         |              |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 648569 | 3986773 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 680142  | 829660 | Initial Version   | 08 Jan 2025 |



Product Information Sheet ISO 17034 Reference Material

Page 1/2 Version 1

681387 Lot: 824971

**Ivermectin** 

#### 1. General Information

Formula Expiry Date 01 May 2029

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

CAS-No. 70288-86-7

#### Batch Analysis

| Identity                                    | confirmed by NMR, LC-MS       |                             |              |  |  |
|---|-------------------------------|-----------------------------|--------------|--|--|
| Overall Purity                              | 92.03 % (g/g)                 | <b>Expanded Uncertainty</b> | 0.95 % (g/g) |  |  |
| Assay Purity (HPLC)<br>Water (Karl-Fischer) | 96.79 % (g/g)<br>0.14 % (g/g) | Uncertainty                 | 0.19 % (g/g) |  |  |
| Residual Solvents                           | 4.66 % (g/g)                  | Uncertainty                 | 0.12 % (g/g) |  |  |
| Inorganic Impurities                        | 0.12 % (g/g)                  | Uncertainty                 | 0.00 % (g/g) |  |  |

Sum of

Ivermectin B1a (C48H74O14), Mol. Weight: 875.09 g mol-1 Ivermectin B1b (C47H72O14), Mol. Weight: 861.07 g mol-1

Certified on 24 Apr 2024

by Alexander Schulze 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 certified values and uncertainties are determined in accordance with ISO 17034 with an 95% confidence level (k=2). Uncertainty is based on the total combined uncertainty, including uncertainties of characterisation, homogeneity and stability testing. The expiry date is based on the current knowledge and holds only for proper storage conditions of 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).

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.





Product Information Sheet ISO 17034 Reference Material

Page 2/2 Version 1

#### **HPLC-Method**

Article 681387 Lot-No. 824971

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

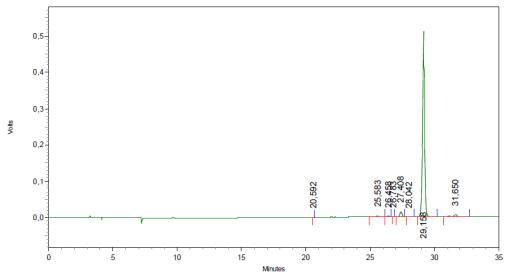
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5 μl

Sample 0.3 mg ml-1 (Acetonitrile)



| Retention Time | Height | Area    | Area Percent       |
|----------------|--------|---------|--------------------|
| 20,592         | 100    | 508     | 0,01               |
| 25,583         | 3780   | 46563   | 0,68               |
| 26,458         | 2193   | 19854   | 0,29               |
| 26,783         | 407    | 2659    | 0,04               |
| 27,408         | 14837  | 152242  | 2,21 Ivermectin E  |
| 28,042         | 314    | 4779    | 0,07               |
| 29,158         | 511454 | 6513630 | 94,69 Ivermectin E |
| 31,650         | 5130   | 138477  | 2,01               |
| Totals         |        |         |                    |
|                | 538215 | 6878712 | 100,00             |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 681387  | 824971 | Initial Version   | 24 Apr 2024 |



Page 1/2 Version 4

01 Sep 2026

20°C (in the dark)

681414 Lot: 805144 Triclabendazole-sulfone

1. General Information

Formula C14H9Cl3N2O3S Expiry Date

Mol. Weight 391.66 g/mol Store at

CAS-No. 106791-37-1

Batch Analysis

Atom%

Identity confirmed

Overall Purity 99.40 % (g/g) Expanded Uncertainty % (g/g)

Assay Purity (HPLC) 99.40 % (g/g) Uncertainty % (g/g)

Certified on 09 Sep 2021

by Heike Uhlig RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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.

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).





Article 681414 Lot-No. 805144

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

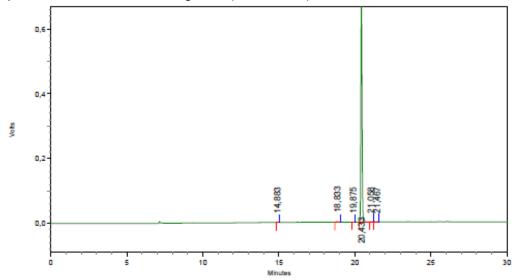
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 2 µl

Sample 0.3 mg ml-1 (Acetonitrile)



| Detector A - 1 (220nm) |
|------------------------|
|------------------------|

| Detector A - 1 (220mm) |        |         |              |
|------------------------|--------|---------|--------------|
| Retention Time         | Height | Area    | Area Percent |
| 14,883                 | 1110   | 5307    | 0,14         |
| 18,833                 | 2062   | 11342   | 0,31         |
| 19,875                 | 129    | 866     | 0,02         |
| 20,433                 | 673682 | 3653066 | 99,43        |
| 21,058                 | 199    | 1814    | 0,05         |
| 21,467                 | 256    | 1666    | 0,05         |
|                        |        |         |              |

| 677438 3674061 | Totals |
|----------------|--------|
|                | 677438 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 3.0     | 681414  | 805144 | Format update     | 09 Sep 2021 |
| 4       | 681414  | 805144 | Text update       | 08 Jun 2023 |



Page 1/2 Version 1

681415 Lot: 829248 Triclabendazole-sulfoxide

1. General Information

Formula C14H9Cl3N2O2S Mol. Weight 375.66 g/mol

**375.66 g/mol** 100648-13-3

Expiry Date Store at

01 Jan 2030

20°C (in the dark)

2. Batch Analysis

CAS-No.

Identity confirmed by LC-MS

Overall Purity 97.13 % (g/g) Expanded Uncertainty 0.54 % (g/g)

Assay Purity (HPLC) 97.13 % (g/g) Uncertainty 0.27 % (g/g)

Certified on 07 Jan 2025

by Jacqueline Seidel RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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** 

#### **HPLC-Method**

Article 681415 Lot-No. 829248

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

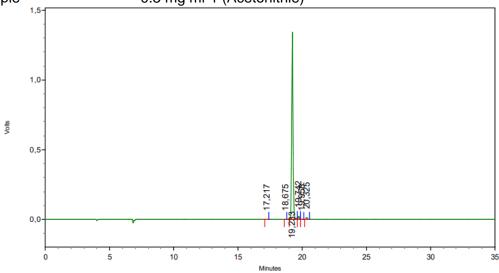
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5µl

Sample 0.3 mg ml-1 (Acetonitrile)



| Detector A - 1 (220nm) |         |         |              |
|------------------------|---------|---------|--------------|
| Retention Time         | Height  | Area    | Area Percent |
| 17,217                 | 492     | 3676    | 0,04         |
| 18,675                 | 330     | 1719    | 0,02         |
| 19,233                 | 1343707 | 8721958 | 97,28        |
| 19,742                 | 22758   | 144101  | 1,61         |
| 19,958                 | 1896    | 14519   | 0,16         |
| 20,325                 | 11749   | 79665   | 0,89         |
|                        |         |         |              |

| Totals |         |         |        |
|--------|---------|---------|--------|
|        | 1380932 | 8965638 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 681415  | 829248 | Initial Version   | 07 Jan 2025 |



Page 1/2 Version 1

681416 Lot: 826995 Clenbuterol hydrochloride

1. General Information

Formula C12H19Cl3N2O Expiry Date 01 Aug 2029

Mol. Weight 313.65 g/mol Store at 20°C (in the dark)

CAS-No. 21898-19-1

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 98.09 % (g/g) Expanded Uncertainty 0.36 % (g/g)

Assay Purity (HPLC) 98.09 % (g/g) Uncertainty 0.18 % (g/g)

Certified on 06 Aug 2024

by Jacqueline Seidel RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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** 

#### **HPLC-Method**

Article 681416 Lot-No. 826995

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

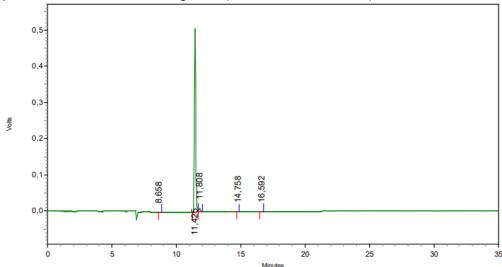
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5 μl

Sample 0.3 mg ml-1 (Acetonitrile/Water 1:1)



| Detector A | - 1 | (220nm) |
|------------|-----|---------|
|            | _   |         |

| Area Percent |
|--------------|
| 0,01         |
| 98,13        |
| 1,72         |
| 0,05         |
| 0,09         |
|              |

| Totals |        |         |        |
|--------|--------|---------|--------|
|        | 517964 | 3998183 | 100,00 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 681416  | 826995 | Initial Version   | 06 Aug 2024 |



Page 1/2 Version 1

683866 Lot: 828551

PAH-Mix 4

#### 1. General Information

Concentration 10.0 µg/ml Expanded Uncertainty 5.0 %

Solvent Acetonitrile Expiry Date 01 Nov 2025

Store at 20°C (in the dark)

#### 2. Composition

|   | Compound             | Conc.[µg/ml] | M.W.[g/mol] | CAS-No   | Formula |
|---|----------------------|--------------|-------------|----------|---------|
| 1 | Benz[a]anthracene    | 10.0         | 228.29      | 56-55-3  | C18H12  |
| 2 | Benzo[a]pyrene       | 10.0         | 252.31      | 50-32-8  | C20H12  |
| 3 | Benzo[b]fluoranthene | 10.0         | 252.31      | 205-99-2 | C20H12  |
| 4 | Chrysene             | 10.0         | 228.29      | 218-01-9 | C18H12  |

Certified on 05 Nov 2024

by Philipp Schwarzenberger RM Release

Awarzenbege-

Instructions for 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. Please mix before usage. If particles or precipitation are detected, sonify until solved. The material is homogenous. There is no minimum sample specified. The material in the vial can be used multiple times, but it is strongly recommended, that all external negative influences for the material are considered and ruled out (e.g. high temperatures, UV-radiation, moisture, oxygen) and that the weight of the bottle between all uses are noted to remain constant to exclude concentration deviations. 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 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.

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





Page 2/2 Version 1

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 683866  | 828551 | Initial Version   | 05 Nov 2024 |



Page 1/2 Version 1

688346 Lot: 828645

**Beclomethasone** 

1. General Information

Formula C22H29ClO5 Expiry Date 01 Nov 2028

Mol. Weight 408.92 g/mol Store at 4°C (in the dark)

CAS-No. 4419-39-0

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 99.58 % (g/g) Expanded Uncertainty 0.34 % (g/g)

Assay Purity (HPLC) 99.58 % (g/g) Uncertainty 0.17 % (g/g)

Certified on 14 Nov 2024

by Jacqueline Seidel RM Release

The overall purity is calculated by: Purity(%) = Assay purity\*(100-water content-impurities)/100

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).





Article 688346 Lot-No. 828645

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

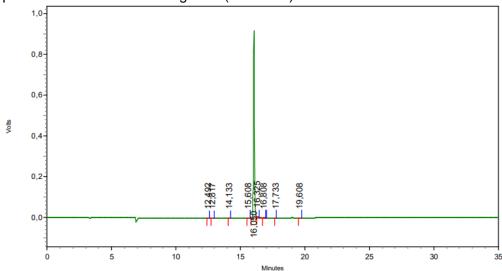
 22.5min
 90
 10

 25min
 90
 10

Flow 1.0 ml min-1 Detector UV-220nm

Injection-Volume 5 µl

Sample 1.0 mg ml-1 (Methanol)



| Detector A - 1 (220nm) |        |      |
|------------------------|--------|------|
| Retention Time         | Height | Area |
| 12,492                 | 130    | 623  |
| 12,817                 | 116    | 662  |
| 14,133                 | 53     | 278  |

| 12,81/ | 110    | 002     | 0,01  |
|--------|--------|---------|-------|
| 14,133 | 53     | 278     | 0,01  |
| 15,608 | 115    | 906     | 0,02  |
| 16,050 | 919126 | 5506087 | 99,56 |
| 16,325 | 3808   | 18816   | 0,34  |
| 16,808 | 231    | 1405    | 0,03  |
| 17,733 | 256    | 1094    | 0,02  |
| 19,608 | 33     | 290     | 0,01  |
|        |        |         |       |
|        |        |         |       |

Totals 923868 5530161 100,00

Exemplary chromatogram of given method.

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 688346  | 828645 | Initial Version   | 14 Nov 2024 |

Area Percent 0,01



Page 1/2 Version 2

689630 Lot: 816109

**Tulathromycin** 

1. General Information

Formula C41H79N3O12 Expiry Date 01 Feb 2028

Mol. Weight 806.08 g/mol Store at -20°C (in the dark)

CAS-No. 217500-96-4

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 97.49 % (g/g) Expanded Uncertainty 1.50 % (g/g)

Assay Purity (HPLC) 97.49 % (g/g) Uncertainty 0.75 % (g/g)

Water <0.01 % (g/g)

contains about 2,4% Tulathromycin B

Certified on 19 Jan 2023

# 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.

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).







Article 689630 Lot-No. 816109

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

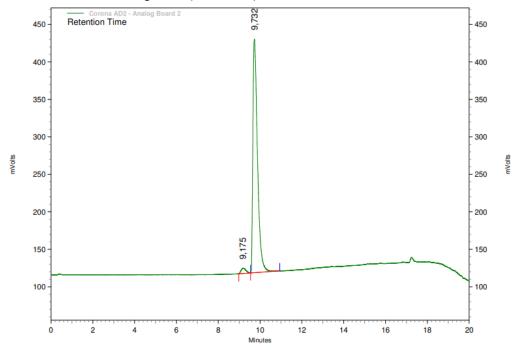
 15min
 95
 5

 20min
 95
 5

Flow 0.7 ml min-1

Detector CAD Injection-Volume 1µI

Sample 1.0 mg ml-1 (Methanol)



Corona AD2 -Analog Board 2 Results

| Retention Time | Height | Area    | Area Percent |
|----------------|--------|---------|--------------|
| 9,175          | 7308   | 115083  | 2,376        |
| 9,732          | 311777 | 4728731 | 97,624       |

| Totals |        |         |         |
|--------|--------|---------|---------|
|        | 319085 | 4843814 | 100,000 |

Peak at RT 9,245 is Tulathromycin B Peak at RT 9,762 is Tulathromycin A

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 689630  | 816109 | Initial Version   | 19 Jan 2023 |
| 2       | 689630  | 816109 | Text update       | 08 Jun 2023 |



Page 1/2 Version 1

689938 Lot: 824127

Gamithromycin

1. General Information

Formula C40H76N2O12 Expiry Date 01 Mar 2028

Mol. Weight 777.04 g/mol Store at 4°C (in the dark)

CAS-No. 145435-72-9

2. Batch Analysis

Identity confirmed by LC-MS

Overall Purity 96.98 % (g/g) Expanded Uncertainty 3.86 % (g/g)

Assay Purity (HPLC) 97.14 % (g/g) Uncertainty 1.93 % (g/g)

Water 0.16 % (g/g)

Certified on 06 Mar 2024

by Oumaima Bouhmaida 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).





Article 689938 Lot-No. 824127

Column Kinetex C18 ; 100 x 4,6mm; 100 A; 2,6µm

Eluent A 0.1 % Formic acid (Acetonitrile)
Eluent B 0.1 % Formic acid (Water)

Gradient time %A %B

 0min
 0
 100

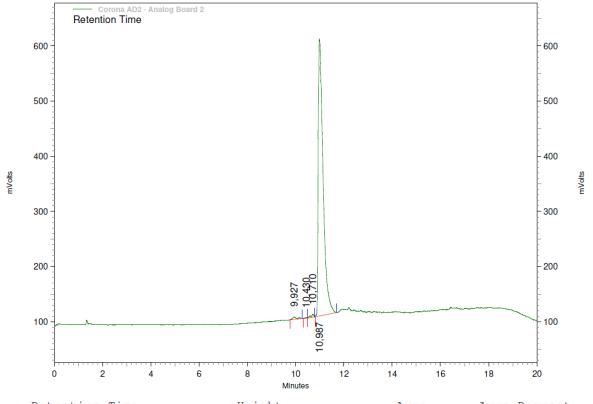
 15min
 95
 5

 20min
 95
 5

Flow 0.7 ml min-1

Detector CAD Injection-Volume 1 µI

Sample 3.0 mg ml-1 (Methanol)



| Retention Time | Height | Area    | Area Percent |
|----------------|--------|---------|--------------|
| 9,927          | 4567   | 54675   | 0,770        |
| 10,430         | 1363   | 7190    | 0,101        |
| 10,710         | 5234   | 44869   | 0,632        |
| 10,987         | 502491 | 6997570 | 98,498       |
|                |        |         |              |

| Totals |        |         |         |
|--------|--------|---------|---------|
|        | 513655 | 7104304 | 100,000 |

| Version | Article | Lot    | Reason for Change | Date        |
|---------|---------|--------|-------------------|-------------|
| 1       | 689938  | 824127 | Initial Version   | 06 Mar 2024 |