



Certificate of Analysis

ISO 9001

Reference Material

Product name

5-(Difluoromethoxy)-2-[[[3,4-dimethoxypyridin-2-yl)methyl]sulphonyl]-1H-benzimidazole (Pantoprazole Sulphone)

Product code

MM0099.02

CAS number

127780-16-9

Molecular weight

399.37

Molecular formula

C₁₆H₁₅F₂N₃O₅S

Lot number

1013078

Appearance

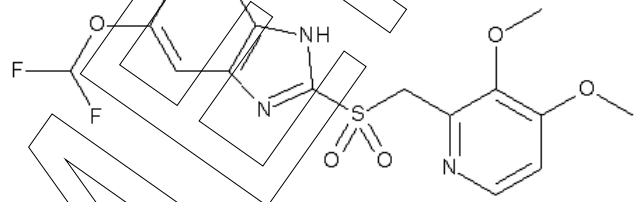
beige solid

Melting point

152 °C

Long-term storage

2 to 8 °C, dark



Assay "as is"
98.9 %

Date of shipment:

02 Sep 2019

Producer confirms that this reference material (RM) meets the specification detailed on this Certificate of Analysis for **two years** from the date of shipment, provided the substance is stored under the recommended conditions unopened in the original container.

| | | | |
|---------------------|--------------------------|--|-----------------|
| Release by: | Date of Release: | | Product Release |
| Dr. Sabine Schröder | Luckenwalde, 05 Aug 2019 | | |



Mikromol™

Product information

For laboratory use only. Not suitable for human or animal consumption.

Before usage of the RM, it should be allowed to warm to room temperature. No drying required, as the certified value is already corrected for the content of water and other volatile materials.

The product quality is controlled by regularly performed quality control tests (retests).

Further content

Identity

Assay

Final result

Revision table

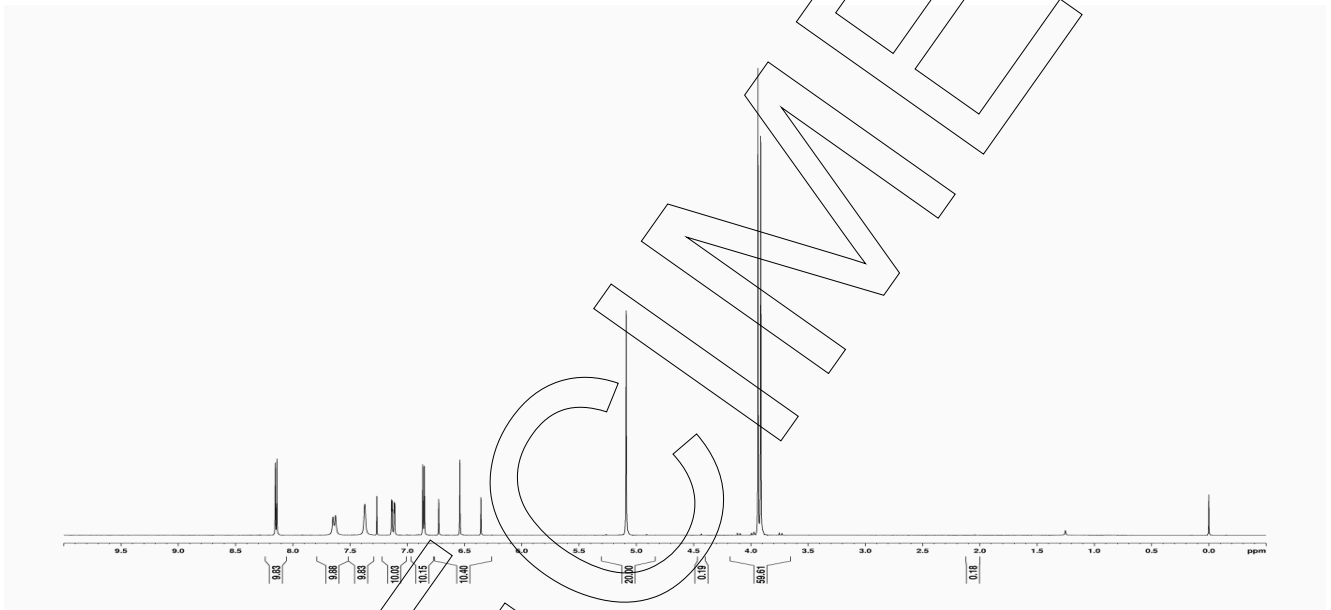
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Identity

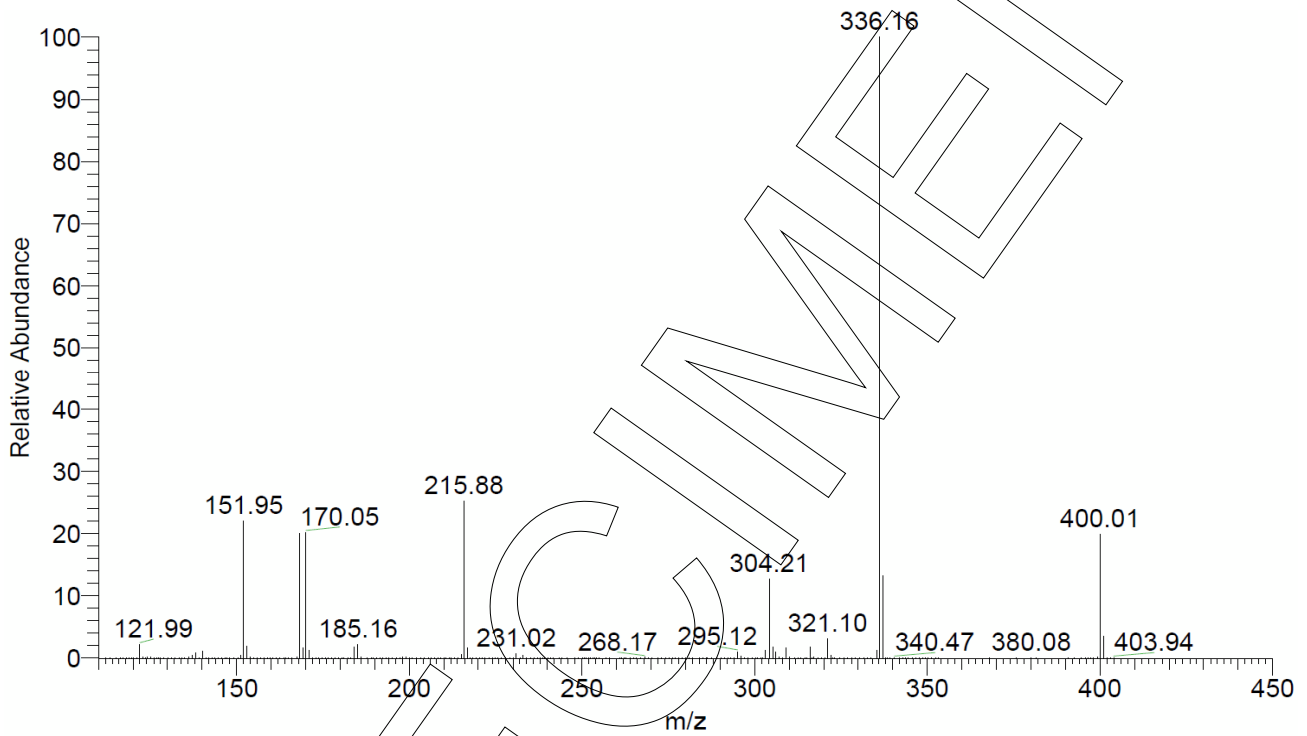
The identity of the reference material was established by following analyses.

| Method | Conditions | Result |
|--------------------|----------------------------|---------------------|
| ¹ H-NMR | 400 MHz, CDCl ₃ | Structure confirmed |





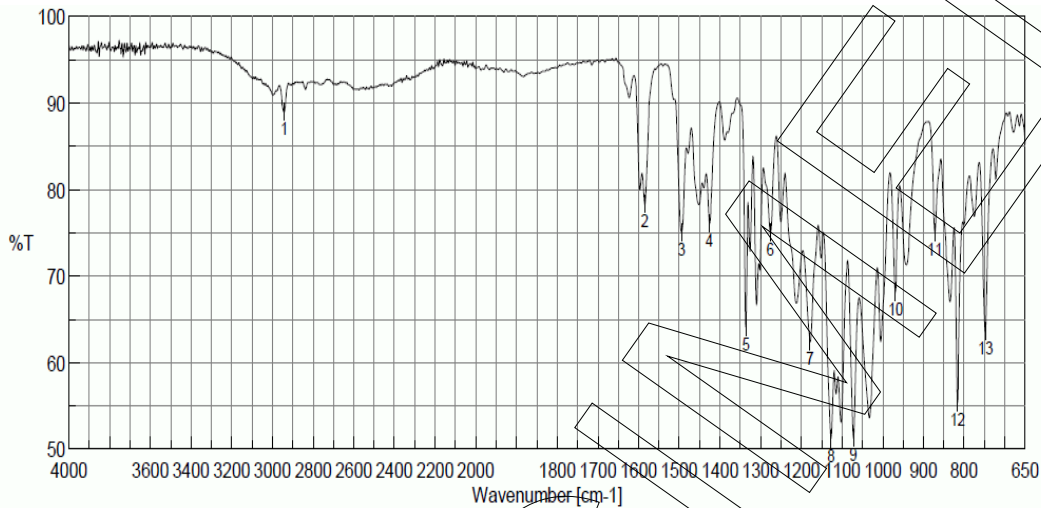
| Method | Conditions | Result |
|--------|---|---------------------|
| MS | 4.5 kV ESI+; vaporization temperature: 200 °C | Structure confirmed |



SPRECHEN



| Method | Conditions | Result |
|--------|--|---------------------|
| IR | Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy | Structure confirmed |



| Result of Peak Picking | | |
|------------------------|----------|-----------|
| No. | Position | Intensity |
| 1 | 2942.84 | 88.9171 |
| 2 | 1585.2 | 78.2505 |
| 3 | 1494.56 | 75.1007 |
| 4 | 1426.1 | 76.0452 |
| 5 | 1336.43 | 64.0552 |
| 6 | 1276.65 | 74.9595 |
| 7 | 1178.29 | 62.369 |
| 8 | 1127.19 | 51.2041 |
| 9 | 1072.23 | 51.2574 |
| 10 | 969.055 | 68.0862 |
| 11 | 871.667 | 75.0182 |
| 12 | 816.706 | 55.3304 |
| 13 | 747.281 | 63.5632 |

Assay

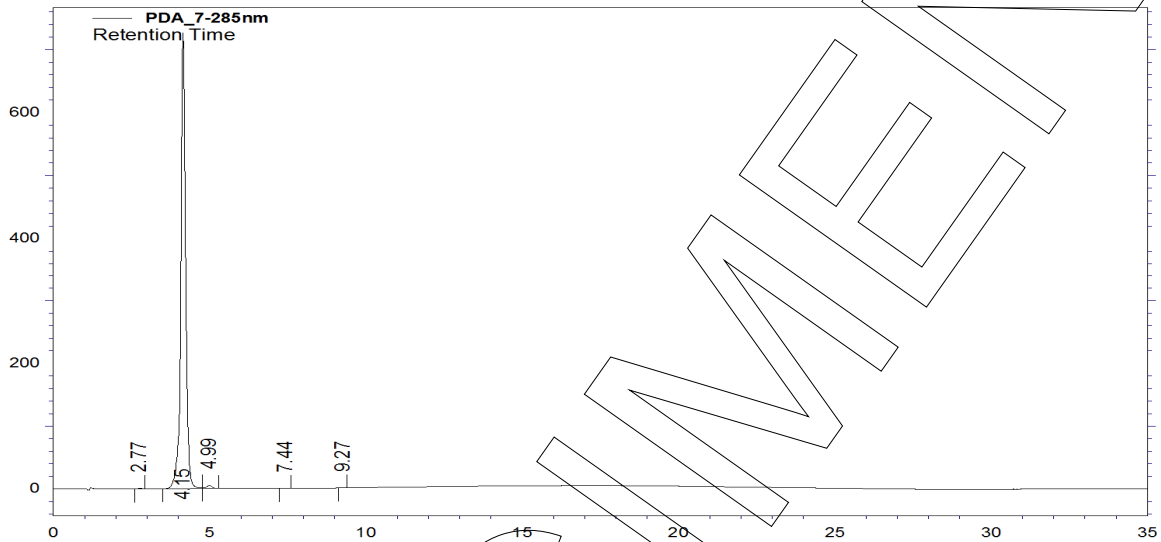
The assay of the reference material was assessed by following analyses.

Purity by High Performance Liquid Chromatography (HPLC)

| HPLC Conditions: | |
|--------------------|---|
| Column | LiChrospher 60 RP-select B; 5 µm, 125 x 4.0 mm |
| Column temperature | 40 °C |
| Detector | DAD, 285 nm |
| Injector | Auto 4 µl; 0.136 mg/ml in Acetonitrile |
| Flow rate | 1.0 ml/min |
| Phase A | Water, 0.1 % H ₃ PO ₄ |
| Phase B | Acetonitrile, 0.1 % H ₃ PO ₄ |
| Gradient program | 0-5 min A/B 70/30 5-15 min A/B to 40/60 15-25 min A/B to 70/30 25-35 min A/B 70/30 (v/v) |



HPLC chromatogram and peak table



Area percent report - sorted by signal

| Pk # | Retention time | Area | Area % |
|---------------|----------------|----------------|---------------|
| 1 | 2.77 | 5977 | 0.08 |
| 2 | 4.15 | 7796225 | 99.12 |
| 3 | 4.99 | 60578 | 0.77 |
| 4 | 7.44 | 1718 | 0.02 |
| 5 | 9.27 | 901 | 0.01 |
| Totals | | 7865399 | 100.00 |

The content of the analyte was determined as ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100 %. System peaks were ignored in calculation.



Result (n = 3)

99.12 %; SD < 0.01 %

Volatile content

Water content

Method

Karl Fischer titration

Result (n = 3)

0.09 %; SD < 0.01 %

Residual solvents

Method

¹H-NMR

Result (n = 1)

Sum: 0.13 %

0.13 % Ethyl acetate

Final result

Assay "as is": 98.90 %

The assay "as is" is assessed by 100% method (mass balance) and is equivalent to the assay based on the not anhydrous and not dried substance respectively.

The calculation of the 100% method follows the formula:

$$\text{Assay (\%)} = (100 \% - \text{volatile contents (\%)}) * \frac{\text{Purity (\%)}}{100 \%}$$

Volatile contents are considered as absolute contributions and purity is considered as relative contribution. Inorganic residues are excluded by additional tests.



Revision table

| Revision | Date | Reason for revision |
|----------|-------------|--|
| 00 | 05 Aug 2019 | Release of the Certificate of Analysis - initial version |

Product warranties for the RM are set out in the terms and conditions of purchase.

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