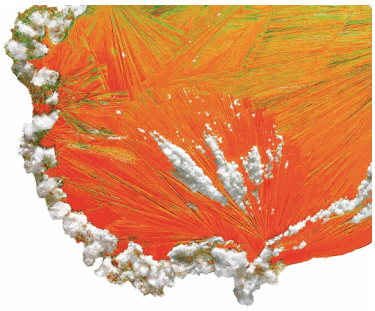
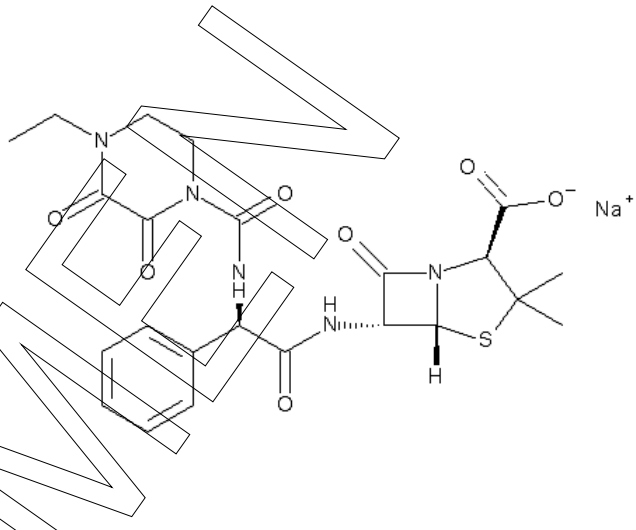


Certificate of Analysis

Reference Material

Product name

Piperacillin Sodium



Product code
MM0296.00

Lot number
1089295

CAS number
59703-84-3

Appearance
white solid

Molecular weight
539.54

Melting point
> 175 °C (dec.)

Molecular formula
$C_{23}H_{26}N_5O_7S$ Na

Long-term storage
-18 °C, dark
very hygroscopic

Assay "as is"
92.6 %

Date of shipment: **09 Aug 2022**

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:**		
Dr. Sabine Schröder	Luckenwalde, 01 Apr 2022		Product Release

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.

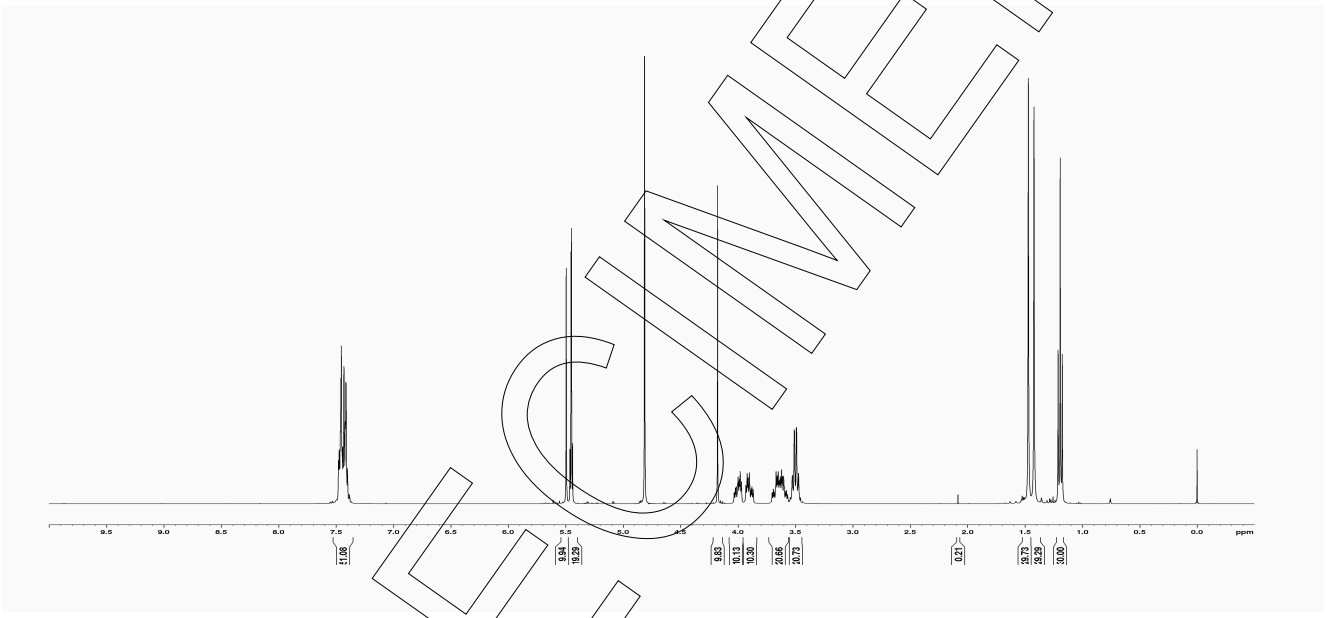
The product quality is controlled by regularly performed quality control tests (retests).

Further content

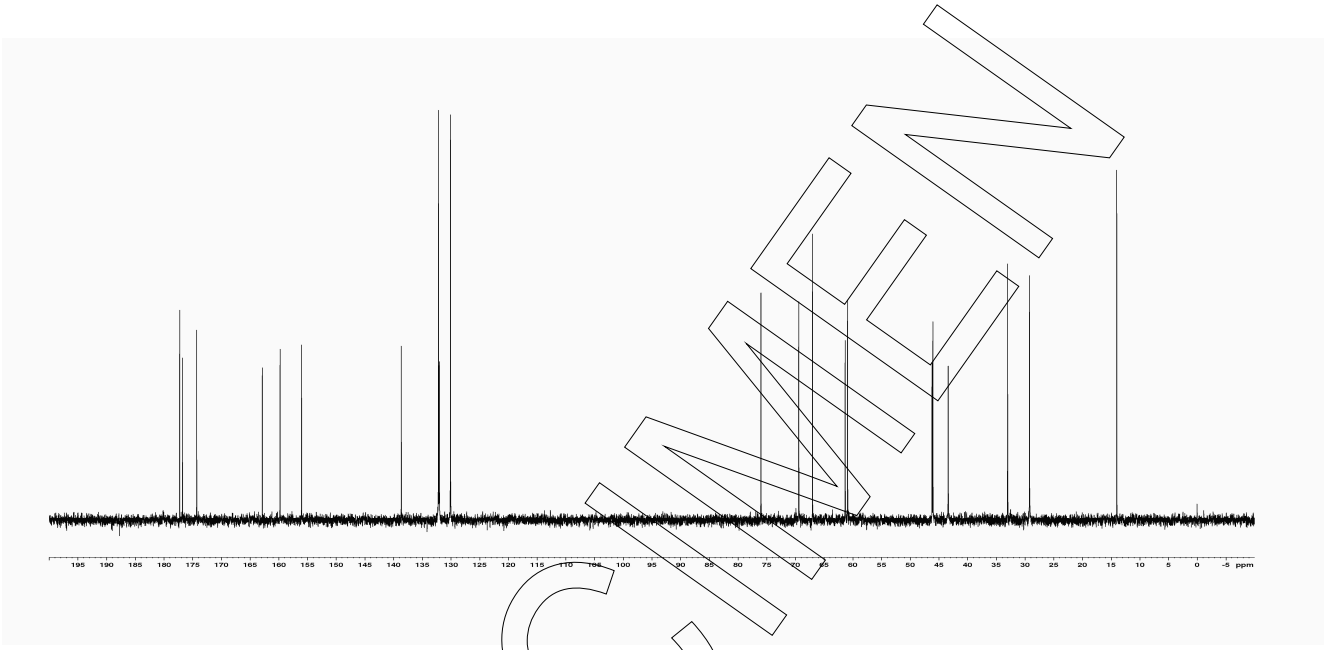
Identity

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

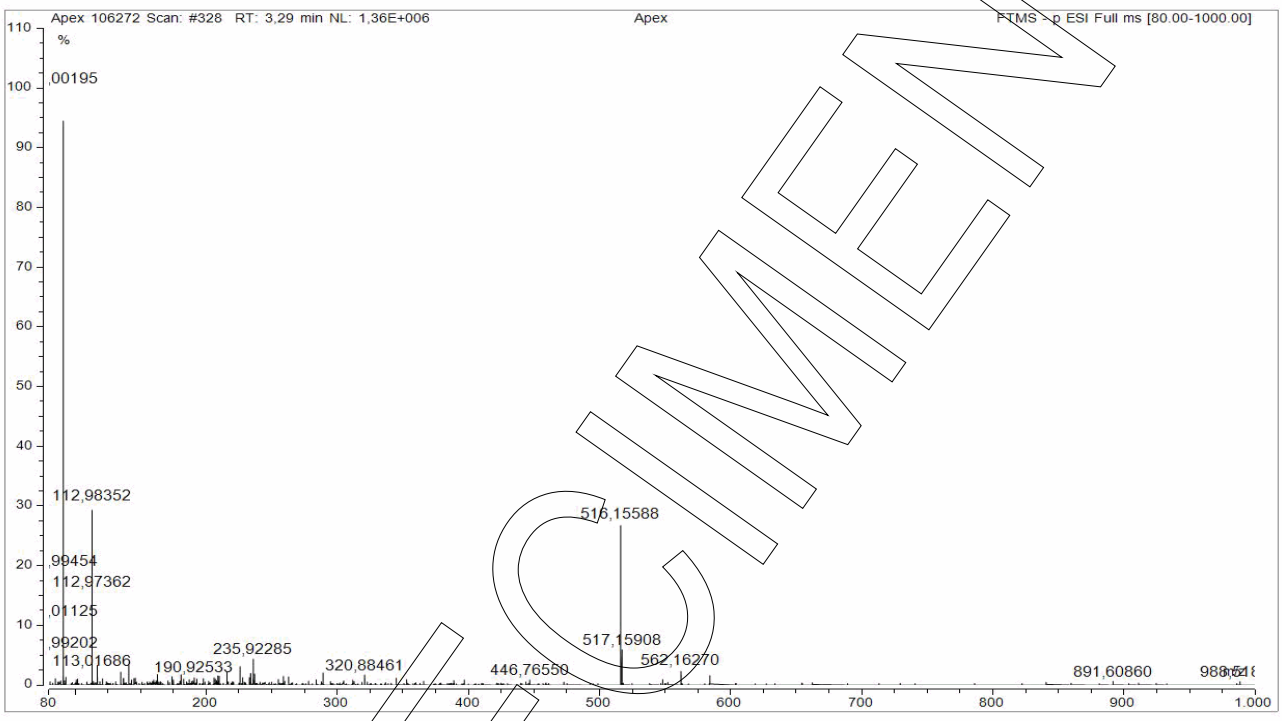
Method	Conditions	Result
^{1}H-NMR	400 MHz, D_2O	Structure confirmed



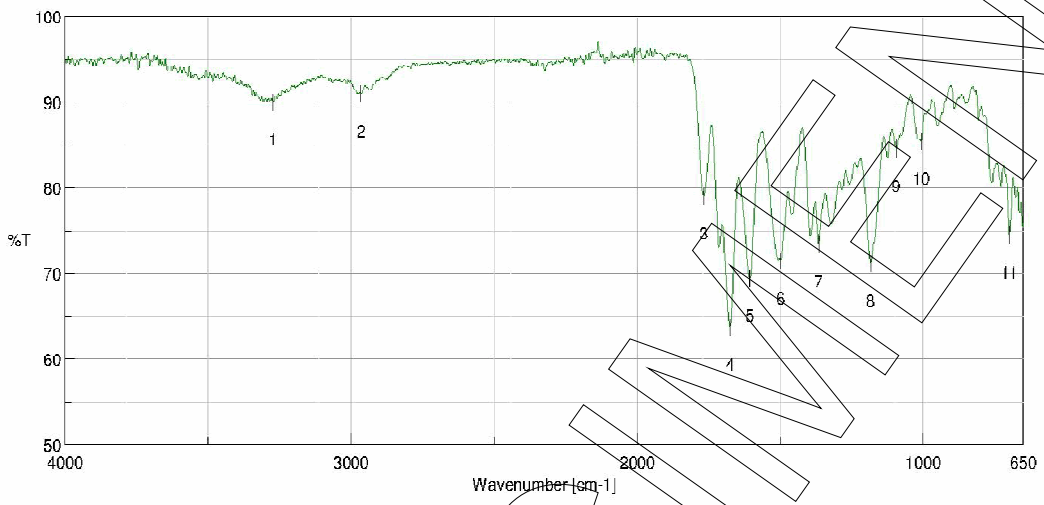
Method	Conditions	Result
^{13}C-NMR	100 MHz, D_2O	Structure confirmed



Method	Conditions	Result
MS	3.2 kV ESI-; capillary temperature: 269 °C Theoretical value: 516.15584	Structure confirmed



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



Results of Peak Find

No.	Position	Intensity
1	3272.61	89.9891
2	2965.02	90.911
3	1766.48	78.9957
4	1674.87	63.6887
5	1605.45	69.4143
6	1497.45	71.4597
7	1365.35	73.397
8	1183.11	71.13
9	1093.44	84.5198
10	1006.66	85.3994
11	699.069	74.395

Method	Conditions	Result
Optical Rotation	c = 1.0 in Water	$[\alpha]D^{20}$ = + 177°

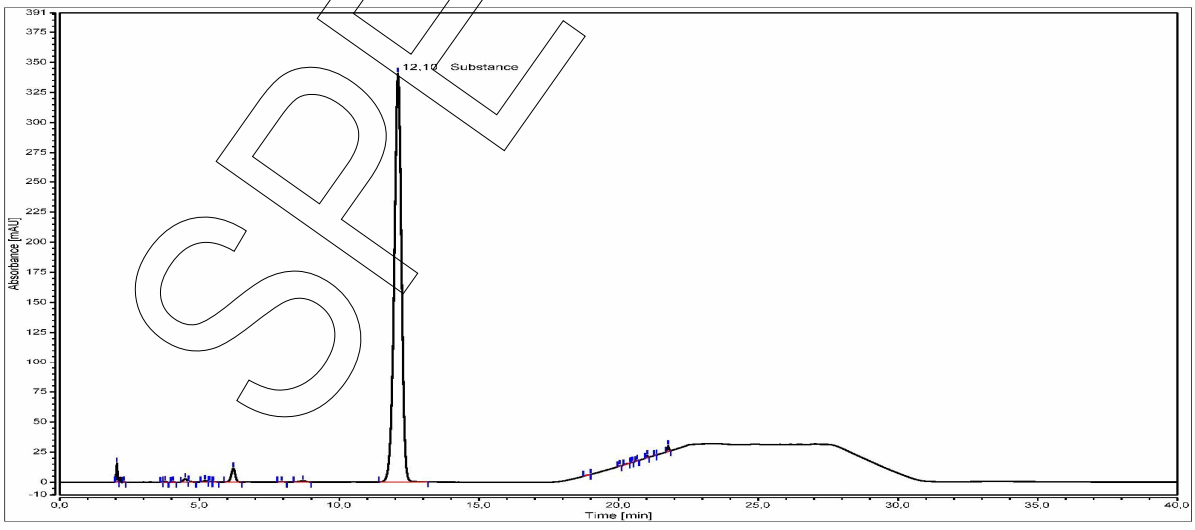
Assay

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

Purity by high performance liquid chromatography (HPLC)

HPLC Conditions:	
Column	Hypersil Gold C18; 5 µm, 150 x 4.6 mm
Column temperature	40 °C
Detector	DAD, 220 nm
Injector	Auto 3 µl; 0.2755 mg/ml in Acetonitrile/Water 50/50 (v/v)
Flow rate	1.0 ml/min
Phase A	Water, 0.1 % H_3PO_4
Phase B	Acetonitrile, 0.1 % H_3PO_4
Gradient program	0-15 min A/B 75/25 15-20 min A/B to 40/60 20-25 min A/B 40/60 25-28 min A/B to 75/25 28-40 min A/B 75/25 (v/v)

HPLC chromatogram and peak table



Area percent report - sorted by signal				
Pk #	**Retention time**	**Area**	**Area %**	
1	2.038	0.8141	0.76	
2	2.288	0.0237	0.02	
3	3.685	0.0152	0.01	
4	3.763	0.0648	0.06	
5	4.050	0.0314	0.03	
6	4.483	0.4068	0.38	
7	4.627	0.0845	0.08	
8	5.197	0.1708	0.16	
9	5.360	0.0620	0.06	
10	5.487	0.0330	0.03	
11	6.207	1.8868	1.77	
12	7.938	0.0328	0.03	
13	8.703	0.2826	0.27	
14	12.103	102.1137	95.78	
15	19.002	0.0255	0.02	
16	20.045	0.0348	0.03	
17	20.403	0.0585	0.05	
18	20.495	0.0198	0.02	
19	20.665	0.0367	0.03	
20	21.025	0.1162	0.11	
21	21.353	0.0093	0.01	
22	21.770	0.2868	0.27	
Totals		**106.6098**	**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 = 10)	95.89 %; SD = 0.04 %

Volatile content

Water content	
Method	Karl Fischer titration
Result (n = 3)	3.29 %; SD = 0.05 %

Residual solvents	
Method	GC headspace
Result (n = 3)	Sum: 0.16 % 0.03 % Acetone; 0.13 % Ethyl acetate

Final result

Assay "as is": **92.58 %**

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	08 Apr 2022	Release of the Certificate of Analysis - initial version

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