

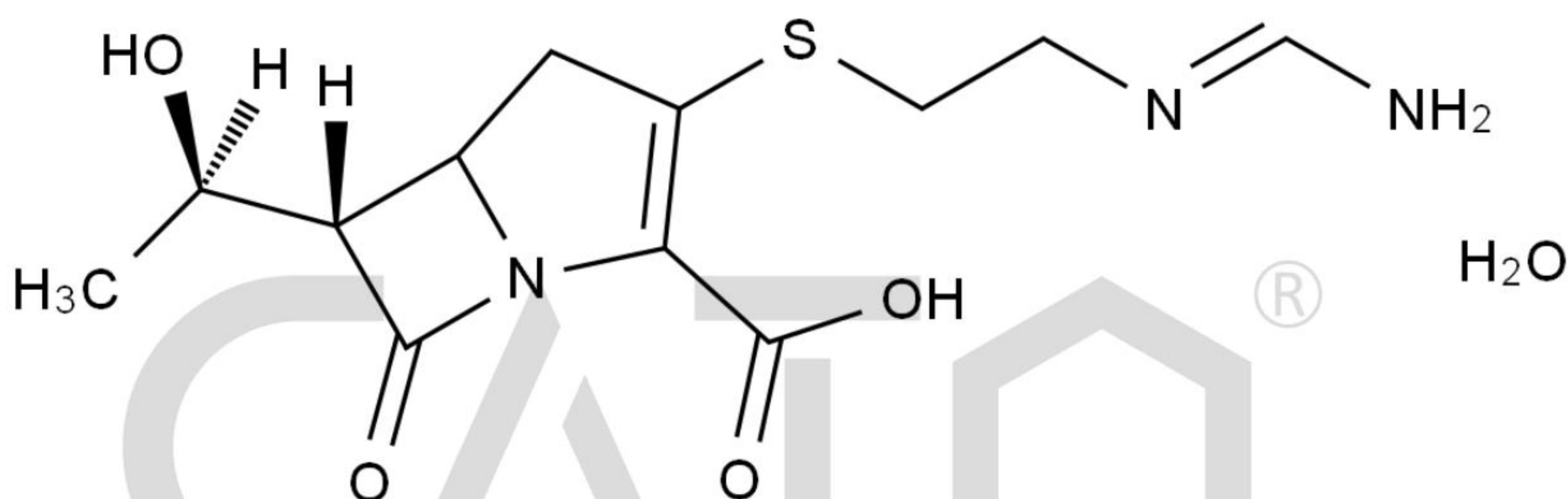
Certificate of Analysis

Reference Material & Standard

Product Name:	Imipenem Monohydrate	Catalogue Number:	CCAD301209
Synonyms:	N/A	Lot Number:	0614-RF-0029
CAS Number:	74431-23-5	Expiry Date:	Jun 20, 2028
Molecular Formula:	C ₁₂ H ₁₇ N ₃ O ₄ S H ₂ O	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	299.35 18.02	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.166%
Water Content	Karl Fischer	6.0434%
Water Content(Free Water)		0.3655%
Assay		98.8%
Uncertainty		±2.0%

Comment:

- The content of crystal water is 5.6779%.
- The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Water Content(Free Water)}) * \text{Purity HPLC (\%)} / 100\%$$
 Water Content(Free Water) is considered as absolute effect, HPLC purity is considered as relative effect.
- The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

Prepared by:

Nice

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Jun 21, 2024

Date: Jun 21, 2024

Date: Jun 21, 2024

