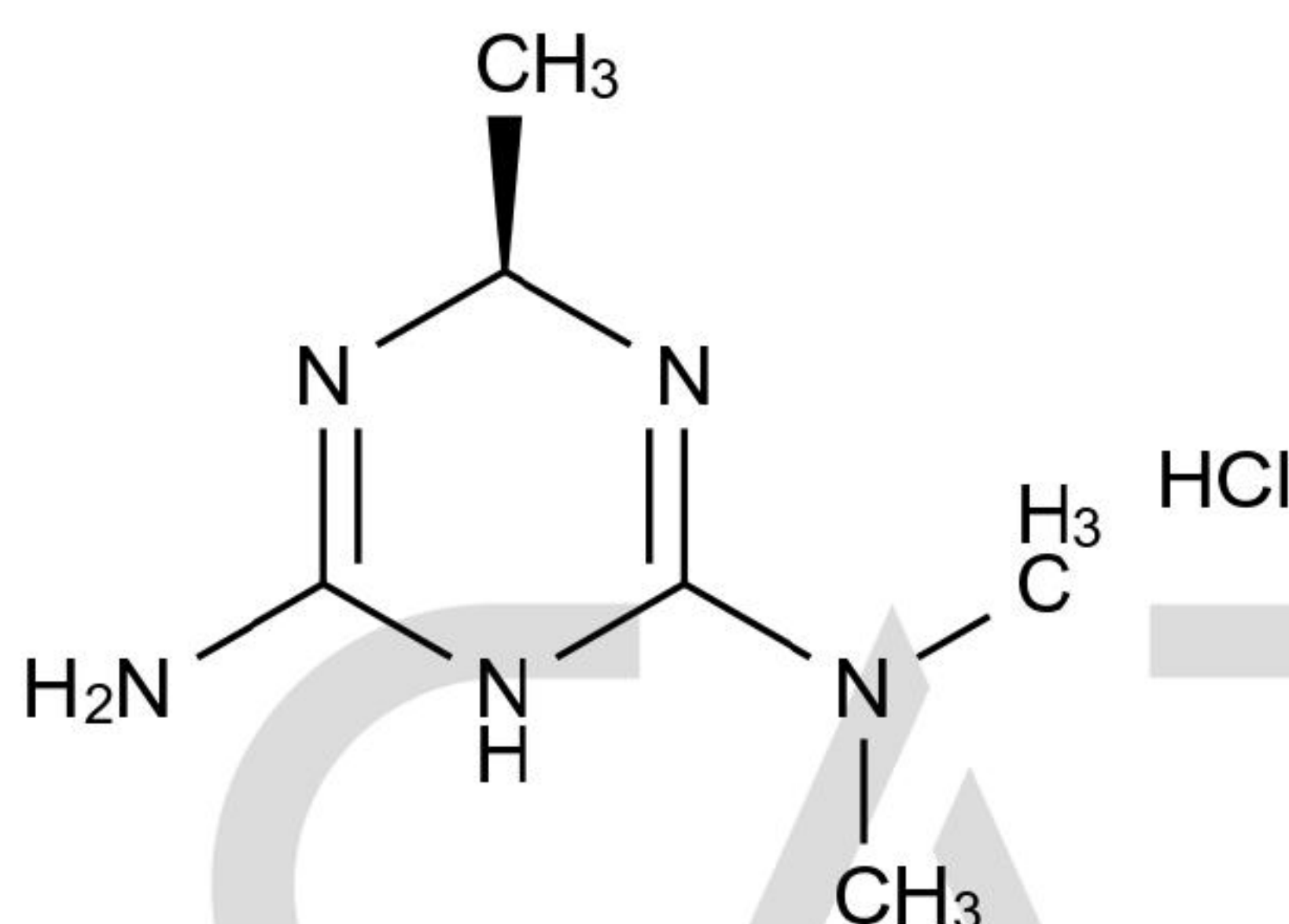


Certificate of Analysis

Reference Material & Standard

Product Name:	Imeglimin hydrochloride	Catalogue Number:	CCAD303968
Synonyms:	N/A	Lot Number:	0217-RG-0103
CAS Number:	775351-61-6	Expiry Date:	Feb 19, 2029
Molecular Formula:	C ₆ H ₁₃ N ₅ HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	155.20 36.46		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Water Content	Karl Fischer	0.1757%
Assay		99.8%
Uncertainty		±2.0%

Comment:

1. The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$\text{Assay (\%)} = (100\% - \text{Water Content}) * \text{Purity HPLC (\%)} / 100\%$

Water Content is considered as absolute effect, HPLC purity is considered as relative effect.

2. 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: Feb 20, 2025

Date: Feb 20, 2025

Date: Feb 20, 2025

