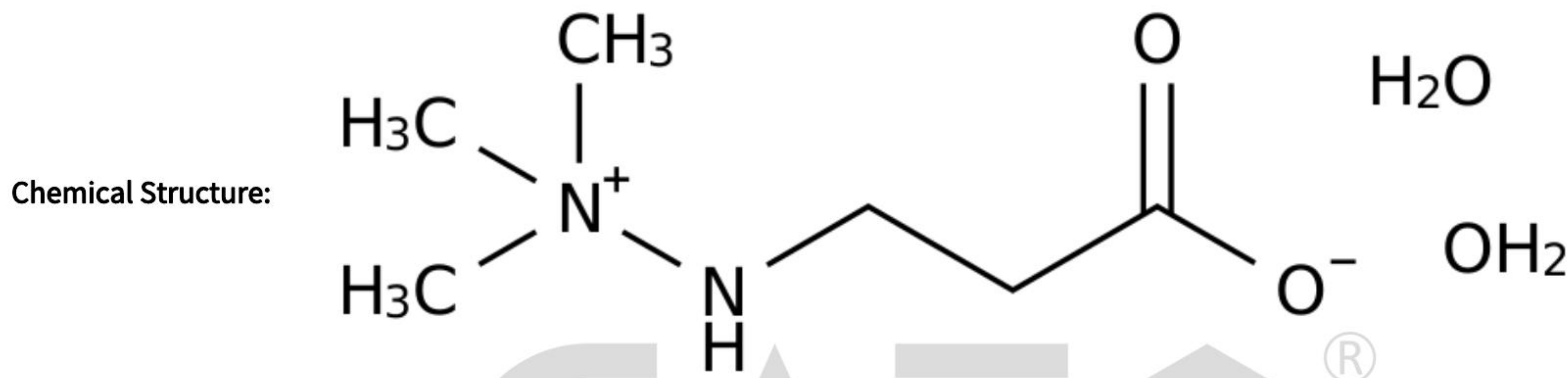


Certificate of Analysis

Reference Material

Product Name:	Meldonium Dihydrate	Catalogue Number:	CCHM703461
Chemical Name:	N/A	Lot Number:	0815-RD-0041
CAS Number:	86426-17-7	Expiry Date:	Jun 29, 2027
Molecular Formula:	C ₆ H ₁₄ N ₂ O ₂ H ₂ O H ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	146.19 18.02 18.02		



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&CNMR&HNMR	Confirmed
Purity	ELSD	99.934%
Loss On Drying	TGA	22.6444%
Loss On Drying(Free Water)		2.9758%
Assay		97.0%
Uncertainty		±2.0%

Comment:

- The content of crystal water is 19.6682%.
- The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Loss On Drying(Free Water)}) * \text{Purity ELSD (\%)} / 100\%$$
 Loss On Drying(Free Water) is considered as absolute effect, ELSD 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:

Lisa

Reviewed by:

Hinlam

Aporoved by General manager:

David

Date: Jun 30, 2023

Date: Jun 30, 2023

Date: Jun 30, 2023

