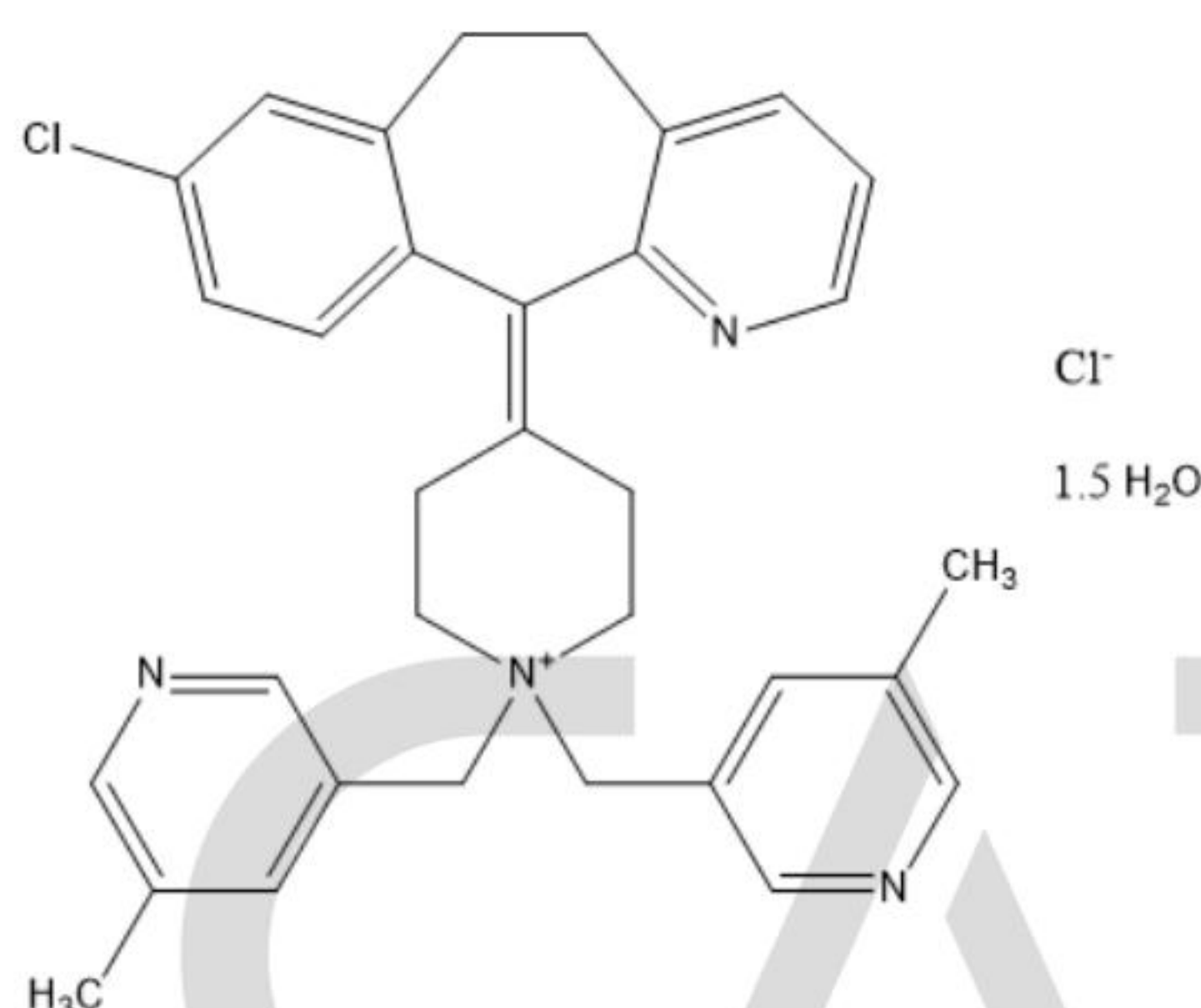


Certificate of Analysis

Reference Material & Standard

Product Name:	Rupatadine Impurity 22 1.5 hydrate	Catalogue Number:	C4X-102722
Synonyms:	N/A	Lot Number:	0701-RF-0109
CAS Number:	N/A	Expiry Date:	Jul 12, 2026
Molecular Formula:	C33H34ClN4 Cl 1.5(H2O)	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	522.10 35.45 1.5(18.02)		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Brown Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.601%
Loss On Drying	TGA	8.035%
Loss On Drying(Free Water)	TGA	3.411%
Assay		96.2%

Comment:

- The content of crystal water is 4.624%.
- The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Loss On Drying(Free Water)}) \times \text{Purity HPLC (\%)} / 100\%$$
 Loss On Drying(Free Water) is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Jul 05, 2024

Date: Jul 05, 2024

Date: Jul 05, 2024

