

Certificate of Analysis

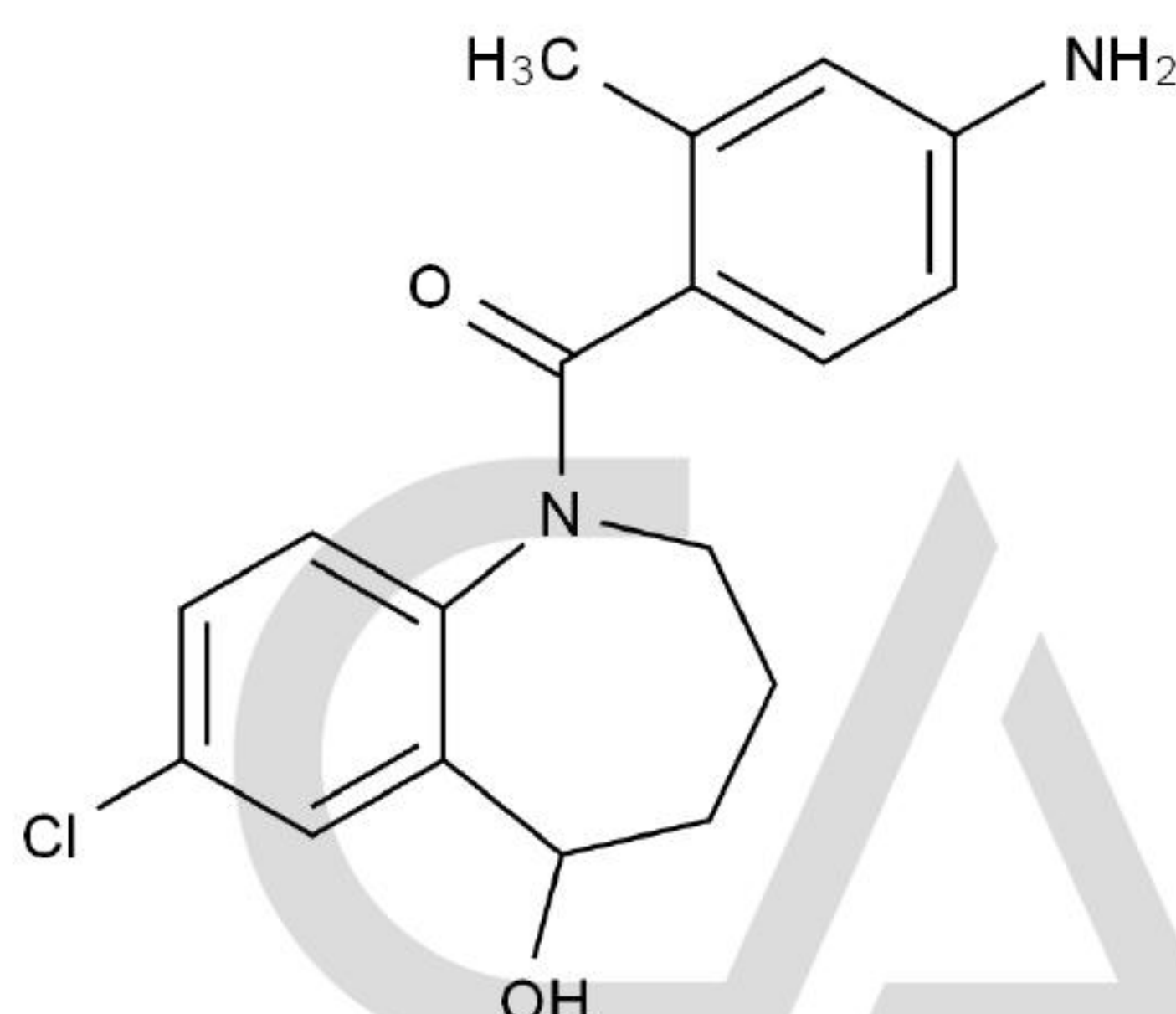
Reference Material & Standard

Product Name:	Tolvaptan Impurity 8	Catalogue Number:	C4X-19558
Synonyms:	N/A	Lot Number:	0912-RE-0053
CAS Number:	1432725-24-0	Expiry Date:	Jan 22, 2030
Molecular Formula:	C ₁₈ H ₁₉ ClN ₂ O ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	330.81	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	96.196%
Residue on Ignition	TGA	0.0469%
Loss On Drying	TGA	1.7752%
Assay		94.4%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Residue on Ignition - Loss On Drying) * Purity HPLC (%) / 100%

Residue on Ignition and Loss On Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

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Reviewed by:

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Approved by General Manager:

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Date: Jan 23, 2026

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