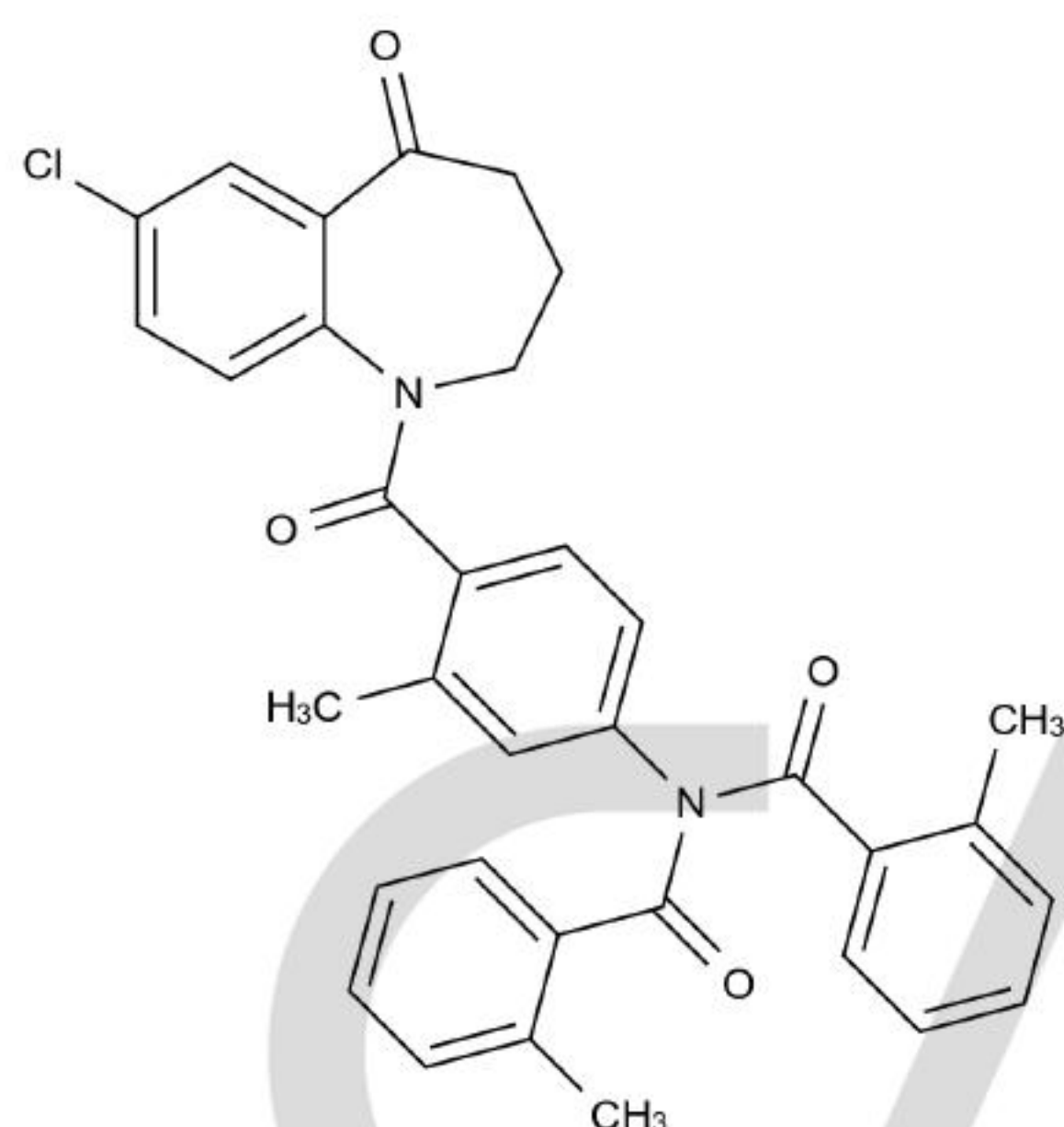


Certificate of Analysis

Reference Material & Standard

Product Name:	Tolvaptan Impurity 59	Catalogue Number:	C4X-195559
Synonyms:	N/A	Lot Number:	0912-RF-0054
CAS Number:	N/A	Expiry Date:	Apr 22, 2027
Molecular Formula:	C ₃₄ H ₂₉ ClN ₂ O ₄	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	565.06		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.410%
Water Content	Karl Fischer	0.26%
Residual Solvents	NMR	Not detected in NMR
Assay		99.2%

Comment:

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

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

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Sep 12, 2024

Date: Sep 12, 2024

Date: Sep 12, 2024

