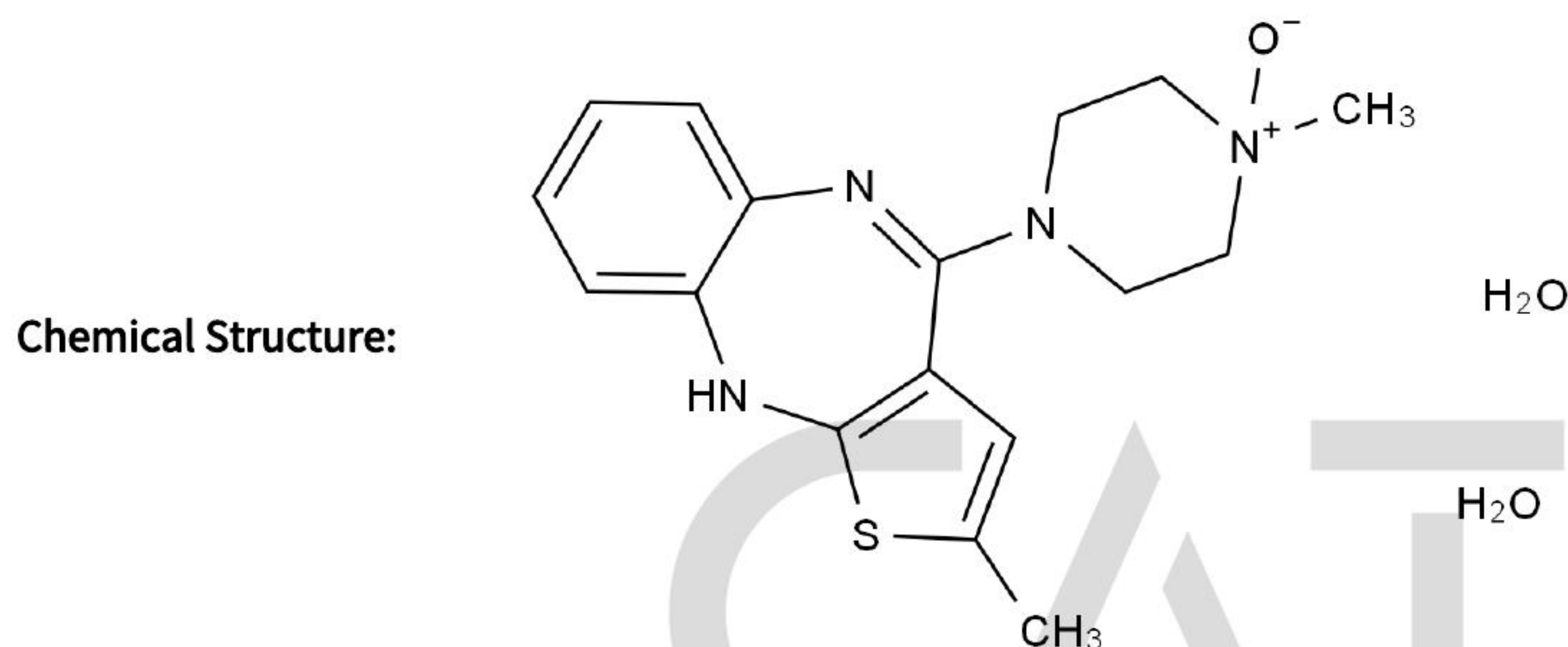


Certificate of Analysis

Reference Material & Standard

Product Name:	Olanzapine EP Impurity D Dihydrate	Catalogue Number:	C4X-117843
Synonyms:	N/A	Lot Number:	0427-RG-0065
CAS Number:	2760465-02-7	Expiry Date:	Apr 23, 2028
Molecular Formula:	C ₁₇ H ₂₀ N ₄ O ₅ 2*H ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	328.43 2*18.02		



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.131%
Water Content	Karl Fischer	9.99%
Water Content(Free Water)	Karl Fischer	0.10%
Residual Solvents	NMR	0.37% acetonitrile
Assay		98.7%

Comment:

- The content of crystal water is 9.89%.
- The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Water Content(Free Water)} - \text{Residual Solvents}) * \text{Purity HPLC (\%)} / 100\%$$
 Water Content(Free Water) 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: Apr 30, 2025

Date: Apr 30, 2025

Date: Apr 30, 2025

