CERTIFICATE OF ANALYSIS

(Certificate No. KMT028067-01)

Release Date: 18/11/2025 **Re-test Date:** 17/11/2028

Tolvaptan Impurity II-A

Identification

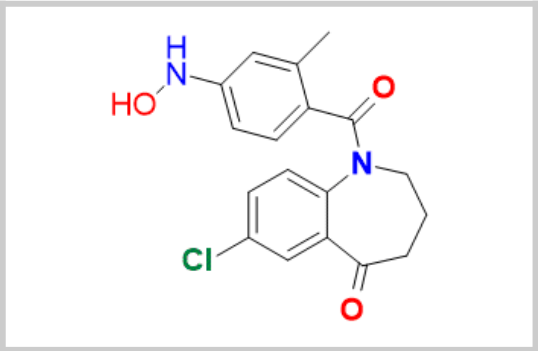
Chemical Name :
7-chloro-1-(4-(hydroxyamino)-2-methylbenzoyl)-3,4-dihydro-1H-benzo[b]azepin-5(2H)-one

CAT No. : KMT028067

CAS No. : Not Available

Molecular Formula : C18H17ClN2O3

Molecular Weight : 344.79



Analytical Information

Batch No. : T028067-114-007

Description : Off White Solid

HPLC Purity : 95.19 %

Weight Loss By TGA : 0.43 %

% Potency : 94.78 %

Solubility : ACN : WATER (1 : 1)

Mass : Confirm

IR : Confirm

1H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be shipped at room temperature

% Potency = [100 - 0.43(Weight Loss By TGA)] x [95.19(HPLC Purity)]/100 = 94.78 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		18/11/2025
Reviewed & Approved By	Quality Control	Parag Patel		18/11/2025

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA