

CERTIFICATE OF ANALYSIS

(Certificate No. KMT028001-01)

Release Date: 31/07/2024

Re-test Date: 30/07/2027

TLV-II STANDARD OF TOLVAPTAN

Identification

Chemical Name :

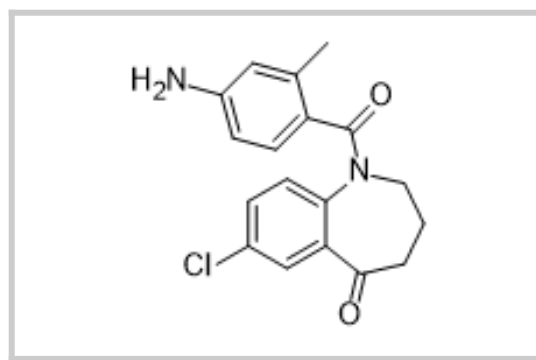
1-(4-amino-2-methylbenzoyl)-7-chloro-3,4-dihydro-1H-benzo[b]azepin-5(2H)-one

CAT No. : KMT028001

CAS No. : 137977-97-0

Molecular Formula : C₁₈H₁₇ClN₂O₂

Molecular Weight : 328.79



Analytical Information

Batch No. : TOL-IMP-10-073-311

Description : Light Orange Solid

HPLC Purity : 93.31 %

Weight Loss By TGA : 0.63 %

% Potency : 92.72 %

Solubility : ACN

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 = $[100 - 0.63(\text{Weight Loss By TGA})] \times [93.31(\text{HPLC Purity})]/100 = 92.72 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		31/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		31/07/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA