

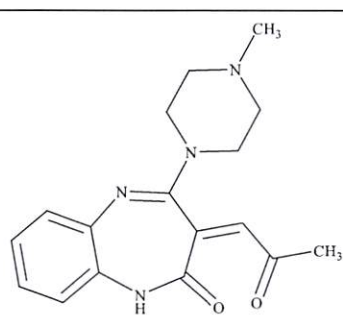
Certificate of Analysis

Certificate No.: 20240809501


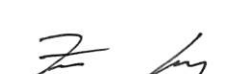
Date: August 9, 2024

Retest date: August 6, 2027

Compound Name: Olanzapine Ketolactam	
Synonyms:	(Z)-4-(4-methylpiperazin-1-yl)-3-(2-oxopropylidene)-1,3-dihydro-2H-benzo[b][1,4]diazepin-2-one
TLC Catalogue Number:	O-019
CAS Number:	1017241-34-7
Molecular Weight:	312.37
Molecular Formula:	C ₁₇ H ₂₀ N ₄ O ₂
Source:	TLC Pharmaceutical Standards
Source Lot No.:	2564-023A3
Storage Conditions:	Hygroscopic, store at 2-8 °C
Solubility:	Methanol



Test Description	Specifications	Results
Visual Description	Yellow solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 90.0%	96.2%
Impurity (HPLC)	RT 2.18, 0.38%; RT 6.76, 2.29%; RT 10.30, 0.29%	
Water Content (KF)	N/A	4.1%
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 85.0%	92.3%
Recommendation:	Release. The compound contains 2.3% E-Isomer (RT 6.76) according to its HPLC and LC-MS.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		08/12/2024
Approved by:	Quality Assurance		08/12/2024

Attachments: HPLC, IR, MS and NMR spectra.