

CERTIFICATE OF ANALYSIS

(Certificate No. KMO007002-01)

Release Date: 17/06/2024

Re-test Date: 16/06/2027

Olanzapine Related Compound B

Identification

Chemical Name :

2-methyl-5,10-dihydro-4H-benzo[b]thieno[2,3-e][1,4]diazepin-4-one

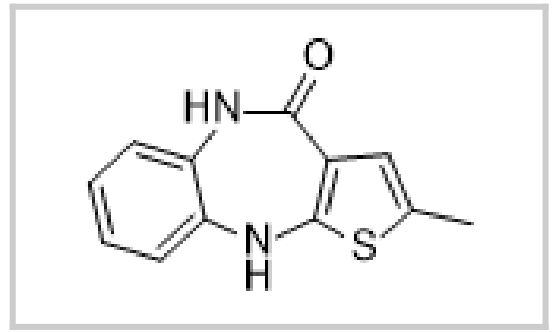
Alt. Name : Olanzapine USP Related Compound B
; Olanzapine Amide Impurity

CAT No. : KMO007002

CAS No. : 221176-49-4

Molecular Formula : C₁₂H₁₀N₂O₂S

Molecular Weight : 230.29



Analytical Information

Batch No. : OLA-EPB-073-263

Description : Yellow Solid

HPLC Purity : 99.74 %

Weight Loss By TGA : 1.30 %

% Potency : 98.44 %

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 - 1.30(Weight Loss By TGA)] x [99.74(HPLC Purity)]/100 = 98.44 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/06/2024
Reviewed & Approved By	Quality Control	Jatin Patel		19/06/2024

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