CERTIFICATE OF ANALYSIS

(Certificate No. KMO007002-01)

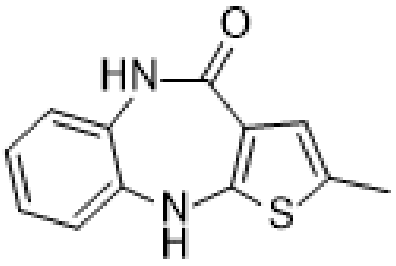
Release Date: 17/06/2024 **Re-test Date:** 16/06/2027

Olanzapine EP Impurity 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	: C12H10N2OS
Molecular Weight	: 230.29



Analytical Information

Batch No.	: OLA-EPB-073-263	**Solubility**	: ACN
Description	: Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 99.74 %	**IR**	: Confirm
Weight Loss By TGA	: 1.30 %	**1H NMR**	: Confirm
% Potency	: 98.44 %	**13C 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 %
-13CNMR added on 23.10.2026

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		23/10/2026
Reviewed & Approved By	Quality Control	Jatin Patel		23/10/2026

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA