CERTIFICATE OF ANALYSIS

(Certificate No. KMO007032-01)

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

Olanzapine Hydroxy Impurity

Identification

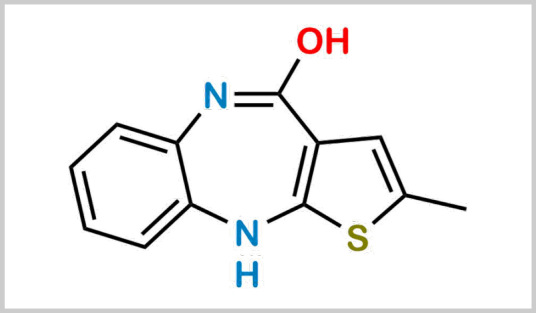
Chemical Name :
2-Methyl-10H-benzo[b]thieno[2,3-e][1,4]diazepin-4-ol

CAT No. : KMO007032

CAS No. : Not Available

Molecular Formula : C12H10N2OS

Molecular Weight : 230.3



Analytical Information

Batch No.	: OLA-EPB-073-263	**Solubility**	: Acetonitrile
Description	: Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 99.74 %	**IR**	: Confirm
Weight Loss By TGA	: 1.30 %	**1H NMR**	: Confirm
% Potency	: 98.44 %		

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		12/04/2025
Reviewed & Approved By	Quality Control	Jatin Patel		12/04/2025

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