CERTIFICATE OF ANALYSIS

(Certificate No. KMO007028-01)

Release Date: 22/10/2026 **Re-test Date:** 21/10/2029

Olanzapine EP Impurity A

Identification

Chemical Name :
5-Methyl-2-[(2-nitrophenyl)amino]thiophene-3-carbonitrile (as per EP); 2-Methyl-10H-thieno-[2,3-b][1,5]benzodiazepin-4[5H]-one (as per USP)

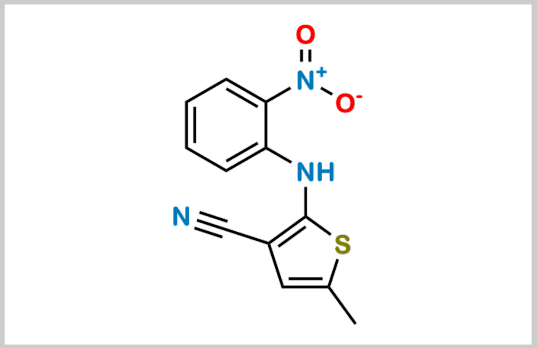
Alt. Name : Olanzapine USP Related Compound A

CAT No. : KMO007028

CAS No. : 138564-59-7

Molecular Formula : C12H9N3O2S

Molecular Weight : 259.3



Analytical Information

Batch No.	: O007028-136-307	**Solubility**	: Acetonitrile
Description	: Brown Solid	**Mass**	: Confirm
HPLC Purity	: 99.90 %	**IR**	: Confirm
Weight Loss By TGA	: 0.31 %	**1H NMR**	: Confirm
% Potency	: 99.59 %	**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 - 0.31(Weight Loss By TGA)] x [99.90(HPLC Purity)]/100 = 99.59 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/10/2026
Reviewed & Approved By	Quality Control	Jatin Patel		22/10/2026

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