

CERTIFICATE OF ANALYSIS

(Certificate No. KML037020-01)

Release Date: 01/01/2025

Re-test Date: 31/12/2027

Lamotrigine EP Impurity A

Identification

Chemical Name :

3-Amino-6-(2,3-dichlorophenyl)-1,2,4-triazin-5(4H)-one

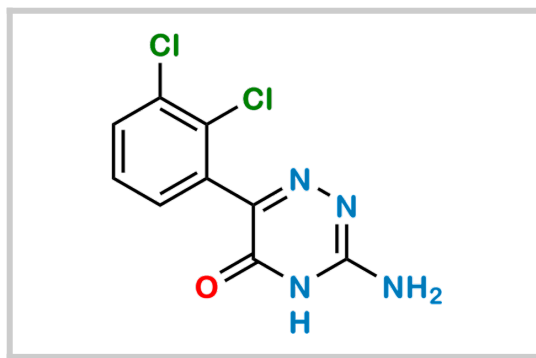
Alt. Name : Lamotrigine USP Related Compound C

CAT No. : KML037020

CAS No. : 252186-78-0

Molecular Formula : C₉H₆Cl₂N₄O

Molecular Weight : 257.1



Analytical Information

Batch No. : L037020-091-118

Description : Off White Solid

HPLC Purity : 99.56 %

Weight Loss By TGA : 0.19 %

% Potency : 99.37 %

Solubility : 0.1% HCl :
Methanol (95 : 5)

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 - 0.19(Weight Loss By TGA)] x [99.56(HPLC Purity)]/100 = 99.37 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		30/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		30/01/2025

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