

CERTIFICATE OF ANALYSIS

(Certificate No. KML037024-01)

Release Date: 24/02/2025

Re-test Date: 23/02/2028

Lamotrigine Impurity E

Identification

Chemical Name :
2,3-Dichlorobenzoic acid

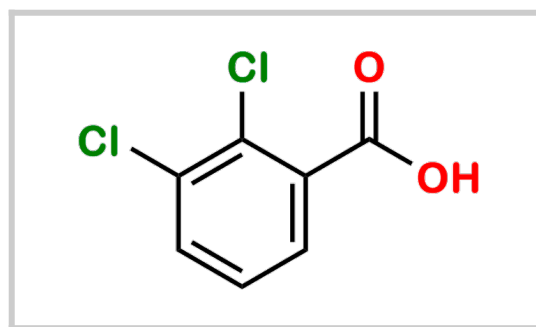
Alt. Name : Lamotrigine USP Related Compound B

CAT No. : KML037024

CAS No. : 50-45-3

Molecular Formula : C₇H₄Cl₂O₂

Molecular Weight : 191.0



Analytical Information

Batch No. : LAM-EP-IMP-E-030-049

Solubility : Acetonitrile

Description : White Solid

Mass : Confirm

HPLC Purity : 99.48 %

IR : Confirm

Weight Loss By TGA : 0.84 %

¹H NMR : Confirm

% Potency : 98.64 %

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 - 0.84(Weight Loss By TGA)] x [99.48(HPLC Purity)]/100 = 98.64 %

-Re-tested on 24.02.2025

-HPLC Purity corrected on 13.03.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		13/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		13/03/2025

Attachments : COA, HPLC, MASS, ¹H NMR, ¹³C NMR, IR and TGA