

# **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

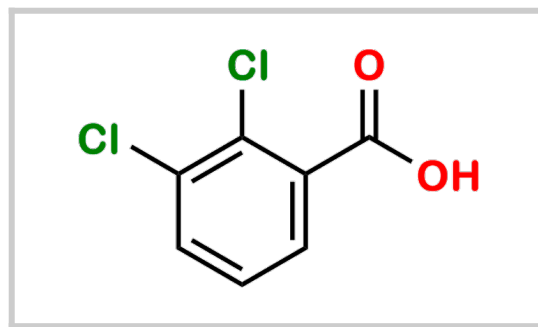
**Alt. Name** : Lamotrigine USP Related Compound  
B

**CAT No.** : KML037024

**CAS No.** : 50-45-3

**Molecular Formula** : C<sub>7</sub>H<sub>4</sub>Cl<sub>2</sub>O<sub>2</sub>

**Molecular Weight** : 191.0



### **Analytical Information**

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

**Description** : White Solid

**HPLC Purity** : 99.48 %

**Weight Loss By TGA** : 0.84 %

**% Potency** : 98.64 %

**Solubility** : Acetonitrile

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C 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, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA