# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMI006005-01)

**Release Date:** 17/11/2025 **Re-test Date:** 16/11/2028

### IVACAFTOR AMINE IMPURITY

### **Identification**

**Chemical Name:** 

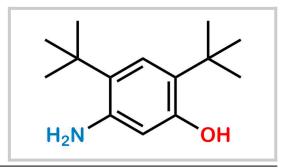
5-Amino-2,4-di-tert-butylphenol

**CAT No.** : KMI006005

**CAS No.** : 873055-58-4

Molecular Formula : C14H23NO

**Molecular Weight** : 221.3



## **Analytical Information**

**Batch No.** : IVAC-AMINE-045-248 **Solubility** : Acetonitrile

Description: Light Brown SolidMass: ConfirmHPLC Purity: 95.05 %IR: ConfirmWeight Loss By TGA: 0.42 %1H NMR: Confirm

**% Potency** : 94.65 %

### **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 - 0.42(Weight Loss By TGA)] x [95.05(HPLC Purity)]/100 = 94.65 %

-Re-tested on 17.11.2025

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/11/2025
Reviewed & Approved By	Quality Control	Jatin Patel		19/11/2025

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