CERTIFICATE OF ANALYSIS

(Certificate No. KMI006005-01)

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

IVACAFTOR AMINE IMPURITY

Identification

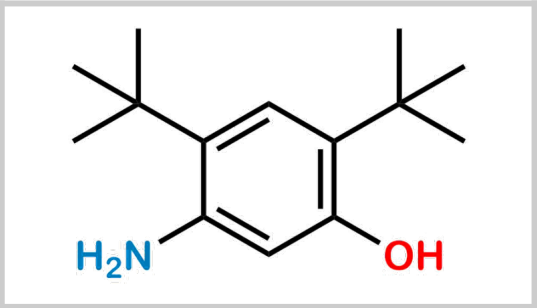
Chemical Name :
5-Amino-2,4-di-tert-butylphenol

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 Solid	**Mass**	: Confirm
HPLC Purity	: 95.05 %	**IR**	: Confirm
Weight 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