CERTIFICATE OF ANALYSIS

(Certificate No. KMI006031-01)

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

IVACAFTOR NITRO PHENOL IMPURITY

Identification

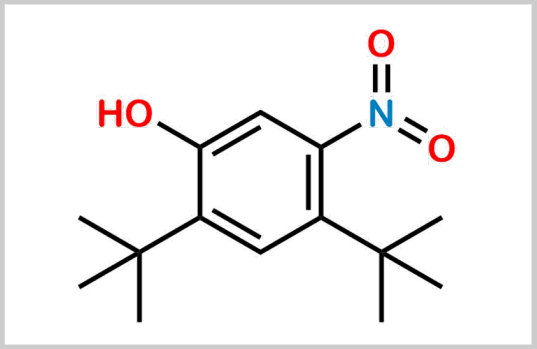
Chemical Name :
2,4-Di-tert-butyl-5-nitrophenol

CAT No. : KMI006031

CAS No. : 873055-57-3

Molecular Formula : C14H21NO3

Molecular Weight : 251.3



Analytical Information

Batch No.	: IVAC-NITRO-030-280	**Solubility**	: Acetonitrile
Description	: Yellow solid	**Mass**	: Confirm
HPLC Purity	: 98.82 %	**IR**	: Confirm
Weight Loss By TGA	: 0.20 %	**1H NMR**	: Confirm
% Potency	: 98.62 %		

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 - 0.20(Weight Loss By TGA)] x [98.82(HPLC Purity)]/100 = 98.62 %
-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