

CERTIFICATE OF ANALYSIS

(Certificate No. KMI006038-01)

Release Date: 17/11/2025

Re-test Date: 16/11/2028

3,5- IVACAFTOR IMPURITY

Identification

Chemical Name :

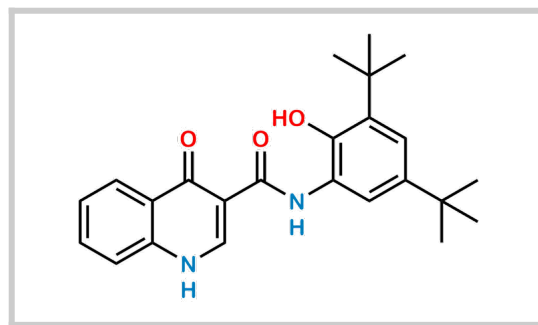
N-(3,5-Di-tert-butyl-2-hydroxyphenyl)-4-oxo-1,4-dihydroquinoline-3-carboxamide

CAT No. : KMI006038

CAS No. : 873051-52-6

Molecular Formula : C₂₄H₂₈N₂O₃

Molecular Weight : 392.5



Analytical Information

Batch No. : IVAC-ISO-030-293

Description : Off White Solid

HPLC Purity : 99.64 %

Weight Loss By TGA : 2.00 %

% Potency : 97.65 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H 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 - 2.00(Weight Loss By TGA)] x [99.64(HPLC Purity)]/100 = 97.65 %

-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