CERTIFICATE OF ANALYSIS

(Certificate No. KMI006012-01)

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

IVACAFTOR ETHYL ESTER IMPURITY

Identification

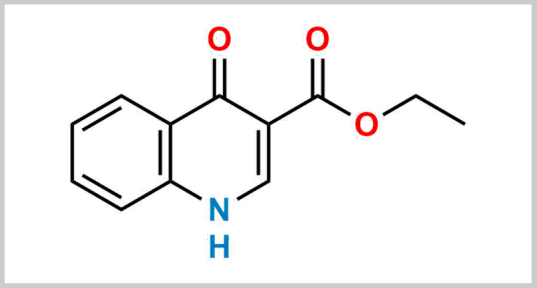
Chemical Name :
Ethyl 4-oxo-1,4-dihydroquinoline-3-carboxylate

CAT No. : KMI006012

CAS No. : 52980-28-6

Molecular Formula : C12H11NO3

Molecular Weight : 217.2



Analytical Information

Batch No.	: IVAC-EE-030-278	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 93.71 %	**IR**	: Confirm
Weight Loss By TGA	: 0.60 %	**1H NMR**	: Confirm
% Potency	: 93.15 %		

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 - 0.60(Weight Loss By TGA)] x [93.71(HPLC Purity)]/100 = 93.15 %
-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