

CERTIFICATE OF ANALYSIS

(Certificate No. KML014024-01)

Release Date: 31/12/2024

Re-test Date: 30/12/2027

Lenalidomide Impurity B

Identification

Chemical Name :

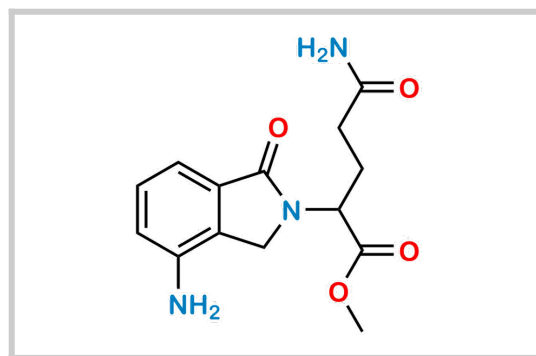
2-(4-Amino-1-oxo-1,3-dihydro-isindol-2-yl)-4-carbamoyl-butyric acid methyl ester ; Methyl 2-(4-amino-1-oxoisindolin-2yl)4-carbamoylbutanoate

CAT No. : KML014024

CAS No. : 1240215-87-5

Molecular Formula : C₁₄H₁₇N₃O₄

Molecular Weight : 291.3



Analytical Information

Batch No. : L014024-091-114

Description : Off White Solid

HPLC Purity : 99.18 %

Weight Loss By TGA : 0.25 %

% Potency : 98.93 %

Solubility : 0.1% OPA :
Methanol (75 : 25)

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 - 0.25(Weight Loss By TGA)] x [99.18(HPLC Purity)]/100 = 98.93 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/01/2025

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