

CERTIFICATE OF ANALYSIS

(Certificate No. KMN002075-01)

Release Date: 10/08/2025

Re-test Date: 09/08/2028

Nintedanib N-Methyl Impurity

Identification

Chemical Name :

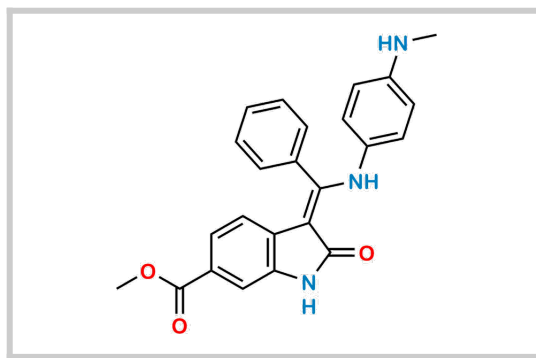
Methyl (Z)-3-(((4-(methylamino)phenyl)amino)(phenyl)methylene)-2-oxoindoline-6-carboxylate

CAT No. : KMN002075

CAS No. : 1987887-92-2

Molecular Formula : C₂₄H₂₁N₃O₃

Molecular Weight : 399.5



Analytical Information

Batch No. : NIN-N-ME-030-225

Description : Light Yellow Solid

HPLC Purity : 99.12 %

Weight Loss By TGA : 1.80 %

% Potency : 97.34 %

Solubility : Methanol

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 - 1.80(Weight Loss By TGA)] x [99.12(HPLC Purity)]/100 = 97.34 %

-Re-tested on 10.08.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		12/02/2026
Reviewed & Approved By	Quality Control	Jatin Patel		12/02/2026

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA