

CERTIFICATE OF ANALYSIS

(Certificate No. KMN002019-01)

Release Date: 13/06/2025

Re-test Date: 12/06/2028

Nintedanib Acetyl Impurity

Identification

Chemical Name :

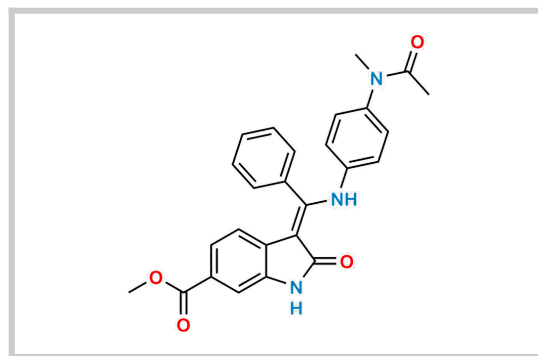
Methyl (Z)-3-(((4-(N-methylacetamido)phenyl)amino)(phenyl)methylene)-2-oxoindoline-6-carboxylate

CAT No. : KMN002019

CAS No. : 1139458-48-2

Molecular Formula : C₂₆H₂₃N₃O₄

Molecular Weight : 441.5



Analytical Information

Batch No. : NIN-ACE-030-228

Description : Yellow Solid

HPLC Purity : 98.53 %

Weight Loss By TGA : 0.79 %

% Potency : 97.75 %

Solubility : ACN : THF (5:5)

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 - 0.79(Weight Loss By TGA)] x [98.53(HPLC Purity)]/100 = 97.75 %
-Re-tested on 13.06.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		14/06/2025
Reviewed & Approved By	Quality Control	Jatin Patel		14/06/2025

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