CERTIFICATE OF ANALYSIS

(Certificate No. KMN002019-01)

Release Date: 13/06/2025 **Re-test Date:** 12/06/2028

Nintedanib Acetyl Impurity

Identification

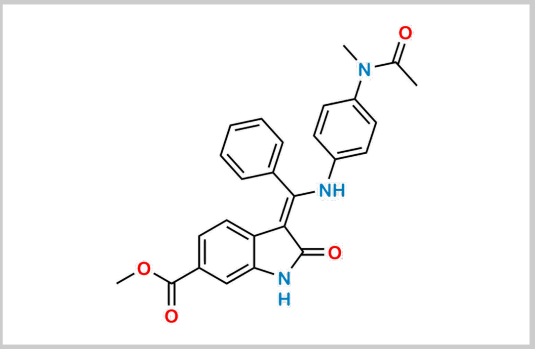
Chemical Name :
Methyl (Z)-3-(((4-(N-methylacetamido)phenyl)amino)(phenyl)methylene)-2-oxoindoline-6-carboxylate

CAT No. : KMN002019

CAS No. : 1139458-48-2

Molecular Formula : C26H23N3O4

Molecular Weight : 441.5



Analytical Information

Batch No.	: NIN-ACE-030-228	**Solubility**	: ACN : THF (5:5)
Description	: Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 98.53 %	**IR**	: Confirm
Weight Loss By TGA	: 0.79 %	**1H NMR**	: Confirm
% Potency	: 97.75 %		

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