CERTIFICATE OF ANALYSIS

(Certificate No. KMN002087-01)

Release Date: 25/10/2024 **Re-test Date:** 24/10/2027

Nintedanib N,N-Dioxide

Identification

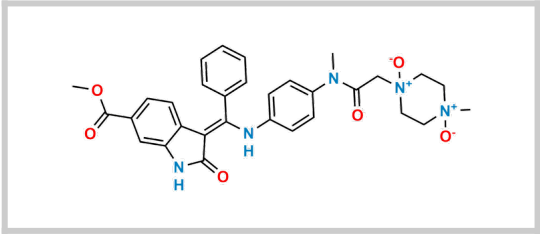
Chemical Name :
(Z)-1-(2-((4-(((6-(methoxycarbonyl)-2-oxoindolin-3-ylidene)(phenyl)methyl)amino)phenyl)(methyl)amino)-2-oxoethyl)-4-methylpiperazine 1,4-dioxide TFA salt

CAT No. : KMN002087

CAS No. : 2734676-68-5

Molecular Formula : C31H33N5O6 ; CF3CO2H

Molecular Weight : 571.6 ; 114.02



Analytical Information

Batch No.	: N002087-073-425	**Solubility**	: Water
Description	: Light Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 99.10 %	**IR**	: Confirm
Weight Loss By TGA	: 2.62 %	**1H NMR**	: Confirm
% Potency	: 96.5 %		

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 - 2.62(Weight Loss By TGA)] x [99.10(HPLC Purity)]/100 = 96.5 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		25/10/2024

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