

CERTIFICATE OF ANALYSIS

(Certificate No. KMA013152-01)

Release Date: 27/12/2023

Re-test Date: 26/12/2026

Apixaban Nitrosoamide Impurity

Identification

Chemical Name :

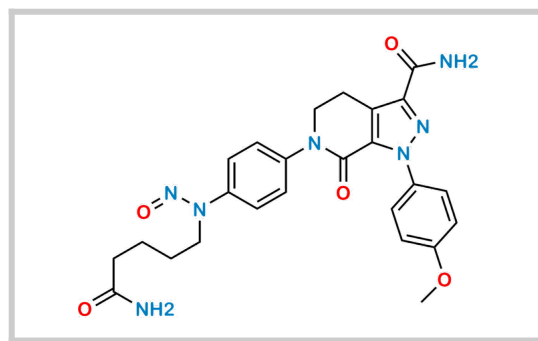
6-(4-((5-Amino-5-oxopentyl)(nitroso)amino)phenyl)-1-(4-methoxyphenyl)-7-oxo-4,5,6,7-tetrahydro-1H-pyrazolo[3,4-c]pyridine-3-carboxamide

CAT No. : KMA013152

CAS No. : Not Available

Molecular Formula : C₂₅H₂₇N₇O₅

Molecular Weight : 505.5



Analytical Information

Batch No. : APX-AMIDE-NO-073-008

Description : Off white solid

HPLC Purity : 99.26 %

Weight Loss By TGA : 1.71 %

% Potency : 97.56 %

Solubility : Acetonitrile

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 - 1.71(Weight Loss By TGA)] x [99.26(HPLC Purity)]/100 = 97.56 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		29/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		29/01/2025

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