CERTIFICATE OF ANALYSIS

(Certificate No. KMR002006-01)

Release Date: 01/07/2024 **Re-test Date:** 30/06/2027

Rivaroxaban Nitroso Impurity 1

Identification

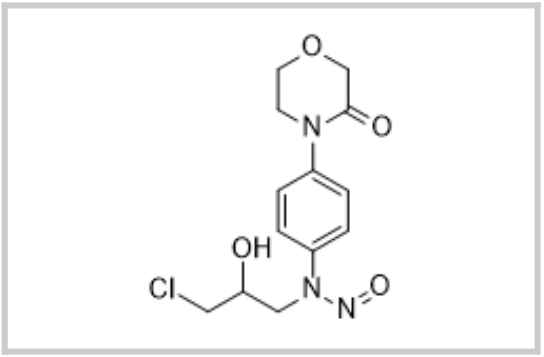
Chemical Name :
N-(3-Chloro-2-hydroxypropyl)-N-(4-(3-oxomorpholino)phenyl)nitrous amide

CAT No. : KMR002006

CAS No. : Not available

Molecular Formula : C13H16ClN3O4

Molecular Weight : 313.74



Analytical Information

Batch No. : RIV-IMP-5-NO-073-274

Description : Light Yellow Solid

HPLC Purity : 99.85 %

Weight Loss By TGA : 0.18 %

% Potency : 99.67 %

Solubility : *Refer in Additional information

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 - 0.18(Weight Loss By TGA)] x [99.85(HPLC Purity)]/100 = 99.67 %
*Solubility : Insoluble in Water and Freely Soluble in 5.0 mg/2.0 ml methanol.

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		07/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		07/05/2025

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