

CERTIFICATE OF ANALYSIS

(Certificate No. KMR002070-01)

Release Date: 13/12/2024

Re-test Date: 12/12/2027

Rivaroxaban Diimidazole adduct impurity

Identification

Chemical Name :

((4-(3-oxomorpholino)phenyl)azanediyl)bis(3-(1,3-dioxoisindolin-2-yl)propane-2,1-diyl)bis(1H-imidazole-1-carboxylate)

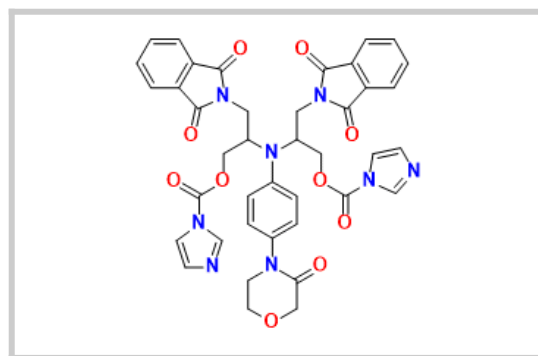
Alt. Name : Rivaroxaban Diimidazole adduct impurity

CAT No. : KMR002070

CAS No. : NA

Molecular Formula : C₄₀H₃₄N₈O₁₀

Molecular Weight : 786.75



Analytical Information

Batch No. : R002070-091-056

Description : Light Yellow Solid

HPLC Purity : 95.42 %

Weight Loss By TGA : 1.37 %

% Potency : 94.11 %

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 - 1.37(Weight Loss By TGA)] x [95.42(HPLC Purity)]/100 = 94.11 %

*Solubility: Insoluble in Water and Freely Soluble in 1mg/0.2 ml methanol

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 13/12/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 13/12/2024 |

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