CERTIFICATE OF ANALYSIS

(Certificate No. KMR002045-01)

Release Date: 22/10/2024 **Re-test Date:** 21/10/2027

Rivaroxaban EP Impurity E

Identification

Chemical Name :
N-[[(5S)-2-oxo-3-[4-(3-oxomorpholin-4-yl)phenyl]-1,3-oxazolidin-5-yl]methyl]thiophene-2-carboxamide (as per EP)

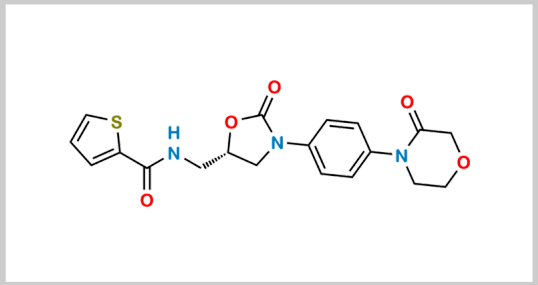
Alt. Name : Rivaroxaban Deschloro Impurity

CAT No. : KMR002045

CAS No. : 1415566-28-7

Molecular Formula : C19H19N3O5S

Molecular Weight : 401.4



Analytical Information

Batch No.	: R002045-073-421	**Solubility**	: ACN : Water (1:1)
Description	: White Solid	**Mass**	: Confirm
HPLC Purity	: 99.01 %	**IR**	: Confirm
Weight Loss By TGA	: 0.26 %	**1H NMR**	: Confirm
% Potency	: 98.75 %		

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 - 0.26(Weight Loss By TGA)] x [99.01(HPLC Purity)]/100 = 98.75 %

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