

# 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)

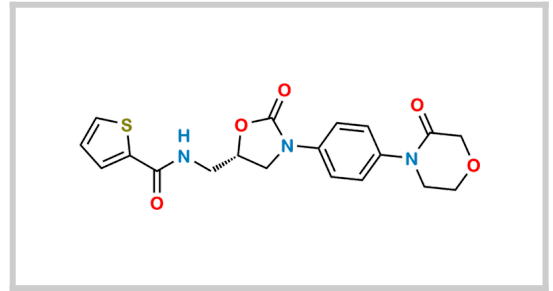
**Alt. Name** : Rivaroxaban Deschloro Impurity

**CAT No.** : KMR002045

**CAS No.** : 1415566-28-7

**Molecular Formula** : C<sub>19</sub>H<sub>19</sub>N<sub>3</sub>O<sub>5</sub>S

**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 %

**<sup>1</sup>H 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** =  $[100 - 0.26(\text{Weight Loss By TGA})] \times [99.01(\text{HPLC Purity})]/100 = 98.75 \%$

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		25/10/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		25/10/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA