

CERTIFICATE OF ANALYSIS

(Certificate No. KME028004-01)

Release Date: 11/12/2024

Re-test Date: 10/12/2027

2-Amino Edoxaban Impurity

Identification

Chemical Name :

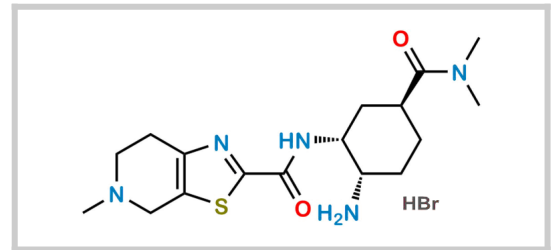
N-((1R,2S,5S)-2-Amino-5-(dimethylcarbamoyl)cyclohexyl)-5-methyl-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridine-2-carboxamide hydrobromide

CAT No. : KME028004

CAS No. : Not Available

Molecular Formula : C₁₇H₂₇N₅O₂S : HBr

Molecular Weight : 365.5 : 80.9



Analytical Information

Batch No. : E028004-091-071

Description : Yellow Hygroscopic Solid

HPLC Purity : 95.75 %

Weight Loss By TGA : 2.45 %

% Potency : 93.4 %

Solubility : Water

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 - 2.45(Weight Loss By TGA)] x [95.75(HPLC Purity)]/100 = 93.4 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		11/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		11/12/2024

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