

CERTIFICATE OF ANALYSIS

(Certificate No. KMF064004-01)

Release Date: 23/03/2026

Re-test Date: 22/03/2029

FLUCLOXACILLIN IMPURITY B

Identification

Chemical Name :

(2RS,4S)-2-[[[3-(2-Chloro-6-fluorophenyl)-5-methyl-1,2-oxazol-4-yl]carbonyl]amino]methyl]-5,5-dimethyl-1,3-thiazolidine-4-carboxylic acid (as per EP)

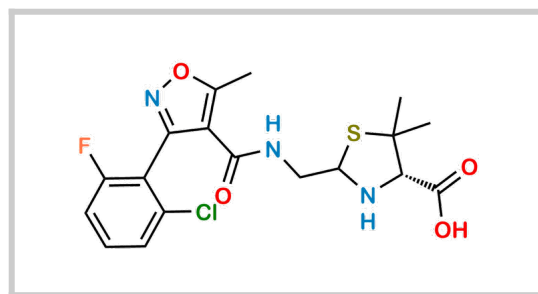
Alt. Name : penilloic acids of flucloxacillin

CAT No. : KMF064004

CAS No. : 1276016-89-7

Molecular Formula : C₁₈H₁₉ClFN₃O₄S

Molecular Weight : 427.9



Analytical Information

Batch No. : SL-YSA-273-042

Description : Beige Solid

HPLC Purity : 90.64 %

Weight Loss By TGA : 2.90 %

% Potency : 88.01 %

Solubility : ACN : 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 = $[100 - 2.90(\text{Weight Loss By TGA})] \times [90.64(\text{HPLC Purity})]/100 = 88.01 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		15/04/2026
Reviewed & Approved By	Quality Control	Jatin Patel		15/04/2026

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA