

CERTIFICATE OF ANALYSIS

(Certificate No. KML008001-01)

Release Date: 31/08/2024

Re-test Date: 30/08/2027

Lacosamide Impurity I

Identification

Chemical Name :

(R)-N-benzyl-2-(3-benzylureido)-3-methoxypropanamide

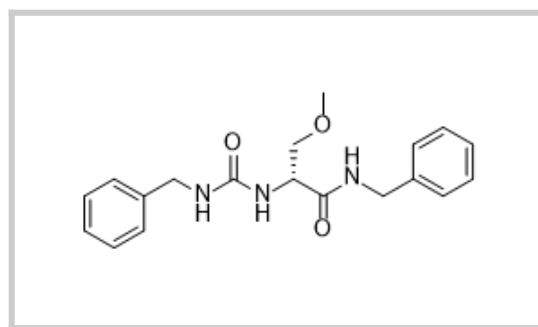
Alt. Name : Ureidolacosamide , Lacosamide EP Impurity I

CAT No. : KML008001

CAS No. : 2295925-90-3

Molecular Formula : C₁₉H₂₃N₃O₃

Molecular Weight : 341.40



Analytical Information

Batch No. : LAC-EP-IMP-I-019-085

Solubility : ACN

Description : Off White solid

Mass : Confirm

HPLC Purity : 91.47 %

IR : Confirm

Weight Loss By TGA : 0.20 %

¹H NMR : Confirm

% Potency : 91.29 %

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 - 0.20(Weight Loss By TGA)] x [91.47(HPLC Purity)]/100 = 91.29 %

-Re-tested on 31.08.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		05/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		05/09/2024

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