

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

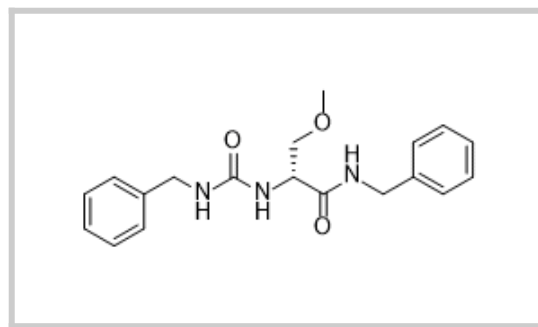
Alt. Name : Ureidolacosamide , Lacosamide EP
Impurity I

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

Description : Off White solid

HPLC Purity : 91.47 %

Weight Loss By TGA : 0.20 %

% Potency : 91.29 %

Solubility : ACN

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 = $[100 - 0.20(\text{Weight Loss By TGA})] \times [91.47(\text{HPLC Purity})]/100 = 91.29 \%$
-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