

# 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

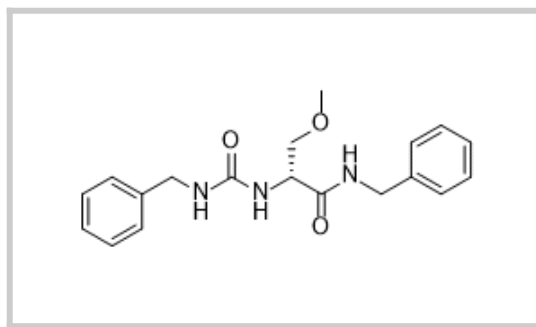
**Alt. Name** : Ureidolacosamide , Lacosamide EP  
Impurity I

**CAT No.** : KML008001

**CAS No.** : 2295925-90-3

**Molecular Formula** : C<sub>19</sub>H<sub>23</sub>N<sub>3</sub>O<sub>3</sub>

**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

**<sup>1</sup>H 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, <sup>1</sup>H NMR, IR and TGA