

CERTIFICATE OF ANALYSIS

(Certificate No. KML008010-01)

Release Date: 25/02/2025

Re-test Date: 24/02/2028

Lacosamide EP Impurity B (R-Isomer)

Identification

Chemical Name :

(2R)-2-(Acetylamino)-3-(acetyloxy)-N-(phenylmethyl)-propanamide

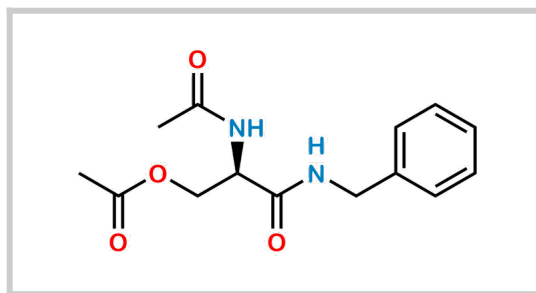
Alt. Name : Lacosamide O-Acetyl Impurity

CAT No. : KML008010

CAS No. : 1318777-54-6

Molecular Formula : C₁₄H₁₈N₂O₄

Molecular Weight : 278.3



Analytical Information

Batch No. : LAC-EP-IMP-B-019-088

Solubility : Methanol

Description : Off white solid

Mass : Confirm

HPLC Purity : 98.04 %

IR : Confirm

Weight Loss By TGA : 0.05 %

¹H NMR : Confirm

% Potency : 97.99 %

¹³C 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 - 0.05(Weight Loss By TGA)] x [98.04(HPLC Purity)]/100 = 97.99 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		25/02/2025

Attachments : COA, HPLC, MASS, ¹H NMR, ¹³C NMR, IR and TGA