CERTIFICATE OF ANALYSIS

(Certificate No. KMP004003-01)

Release Date: 29/05/2025 **Re-test Date:** 28/05/2028

Pregabalin Lactam Impurity

Identification

Chemical Name:

(S)-4-isobutylpyrrolidin-2-one

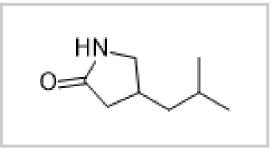
Alt. Name : Pregabalin Lactam

CAT No. : KMP004003

CAS No. : 61312-87-6

Molecular Formula : C8H15NO

Molecular Weight : 141.21



Analytical Information

Batch No. : PRE-LAC-045-192 **Solubility** : Acetonitrile

Description : Light Yellow Liquid Mass : Confirm

HPLC Purity : 98.53 % **IR** : Confirm

Weight Loss By TGA : 2.45 % 1H NMR : Confirm

% Potency : 96.12 %

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 - 2.45(Weight Loss By TGA)] x [98.53(HPLC Purity)]/100 = 96.12 %

-Re-tested on 29.05.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		01/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/10/2025

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