CERTIFICATE OF ANALYSIS

(Certificate No. KMP004003-01)

Release Date: 03/07/2023 **Re-test Date:** 02/07/2026

Pregabalin BP Impurity A

Identification

Chemical Name:

(S)-4-isobutylpyrrolidin-2-one

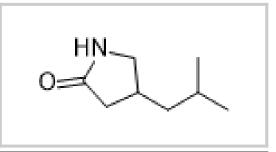
Alt. Name : Pregabalin Lactam

CAT No. : KMP004003

CAS No. : 61312-87-6

Molecular Formula : C8H15NO

Molecular Weight : 141.21



Analytical Information

Batch No. : PRE-LAC-045-192 Solubility : ACN

Description : Light Yellow Liquid Mass : Confirm

HDLC Durity : 08.86.9/

HPLC Purity : 98.86 % IR : Confirm

Weight Loss By TGA : 4.12 % 1H NMR : Confirm

% Potency : 94.79 %

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 - 4.12(Weight Loss By TGA)] x [98.86(HPLC Purity)]/100 = 94.79 %

Remarks: COA Re-generated on 18.05.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		12/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		12/07/2024

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