

CERTIFICATE OF ANALYSIS

(Certificate No. KMP004003-01)

Release Date: 29/05/2025

Re-test Date: 28/05/2028

Pregabalin EP 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 : 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		05/01/2026
Reviewed & Approved By	Quality Control	Jatin Patel		05/01/2026

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