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

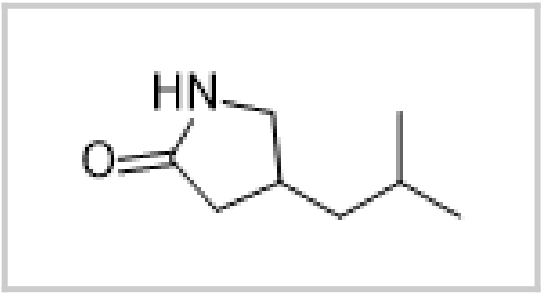
Alt. Name : Pregabalin Lactam

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