CERTIFICATE OF ANALYSIS

(Certificate No. KMP004001-01)

Release Date: 17/10/2025 **Re-test Date:** 16/10/2028

Pregabalin Amide Impurity

Identification

Chemical Name :
(R)-3-(2-amino-2-oxoethyl)-5-methylhexanoic acid

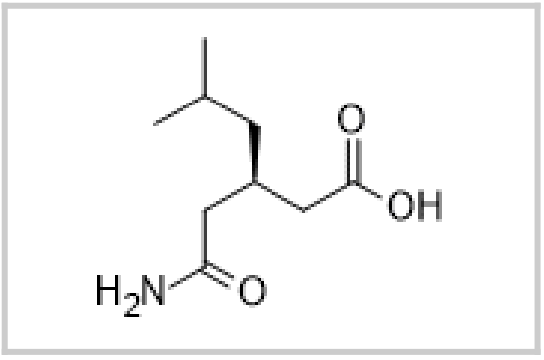
Alt. Name : Pregabalin R-CMH Standard

CAT No. : KMP004001

CAS No. : 181289-33-8

Molecular Formula : C9H17NO3

Molecular Weight : 187.24



Analytical Information

Batch No.	: PRE-(R)-CMH-09-098	**Solubility**	: ACN : Water (1:1)
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 97.74 %	**IR**	: Confirm
Weight Loss By TGA	: 1.02 %	**1H NMR**	: Confirm
% Potency	: 96.74 %	**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 - 1.02(Weight Loss By TGA)] x [97.74(HPLC Purity)]/100 = 96.74 %
-Re-tested on 17.10.2025
-13C NMR added on 04.12.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		04/12/2025
Reviewed & Approved By	Quality Control	Jatin Patel		04/12/2025

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