

CERTIFICATE OF ANALYSIS

(Certificate No. KMP004006-01)

Release Date: 12/07/2024

Re-test Date: 11/07/2027

Pregabalin EP Impurity B

Identification

Chemical Name :

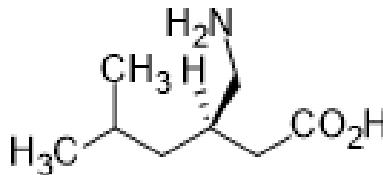
(3R)-3-(aminomethyl)-5-methylhexanoic acid (pregabalin enantiomer)

CAT No. : KMP004006

CAS No. : 148553-51-9

Molecular Formula : C₈H₁₇NO₂

Molecular Weight : 159.23



Analytical Information

Batch No. : PRE-EPB-073-288

Description : Off White Solid

HPLC Purity : 98.24 %

Weight Loss By TGA : 0.99 %

% Potency : 97.27 %

Solubility : ACN

Mass : Confirm

IR : Confirm

¹H 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 - 0.99(Weight Loss By TGA)] x [98.24(HPLC Purity)]/100 = 97.27 %

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