

CERTIFICATE OF ANALYSIS

(Certificate No. KMP004064-01)

Release Date: 26/12/2023

Re-test Date: 25/12/2026

PREGABALIN DIACID IMPURITY

Identification

Chemical Name :

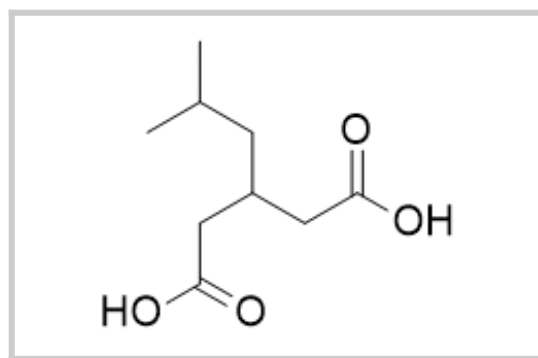
3-Isobutylglutaric Acid ; 3-isobutylpentanedioic acid

CAT No. : KMP004064

CAS No. : 75143-89-4

Molecular Formula : C₉H₁₆O₄

Molecular Weight : 188.2



Analytical Information

Batch No. : PRE-DA-045-372

Description : Light Yellow Liquid

HPLC Purity : 94.18 %

Weight Loss By TGA : 1.33 %

% Potency : 92.93 %

Solubility : Acetonitrile

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 - 1.33(Weight Loss By TGA)] x [94.18(HPLC Purity)]/100 = 92.93 %

Remarks : COA Re-generated on 30.08.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		13/11/2024
Reviewed & Approved By	Quality Control	Jatin Patel		13/11/2024

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