

CERTIFICATE OF ANALYSIS

(Certificate No. KMG002016-01)

Release Date: 24/09/2025

Re-test Date: 23/09/2028

Gabapentin EP Impurity E

Identification

Chemical Name :

1-(Carboxymethyl)cyclohexanecarboxylic acid

Alt. Name

: Gabapentin USP Related Compound
E ; Gabapentin Diacid ;

CAT No.

: KMG002016

CAS No.

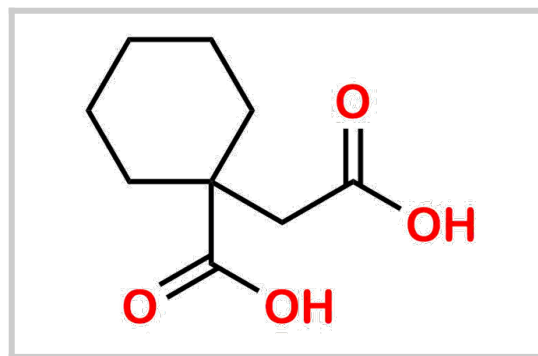
: 67950-95-2

Molecular Formula

: C₉H₁₄O₄

Molecular Weight

: 186.2



Analytical Information

Batch No.

: G002016-210

Mass

: Confirm

Description

: Off white solid

IR

: Confirm

HPLC Purity

: NLT 95.1 %

¹H NMR

: Confirm

Weight Loss By TGA

: NLT 0.1 %

% Potency

: 95 %

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 - 0.1(Weight Loss By TGA)] x [95.1(HPLC Purity)]/100 = 95 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		24/09/2025
Reviewed & Approved By	Quality Control	Jatin Patel		24/09/2025

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