

CERTIFICATE OF ANALYSIS

(Certificate No. KMP004004-01)

Release Date: 30/04/2024

Re-test Date: 29/04/2027

Pregabalin BP Impurity D

Identification

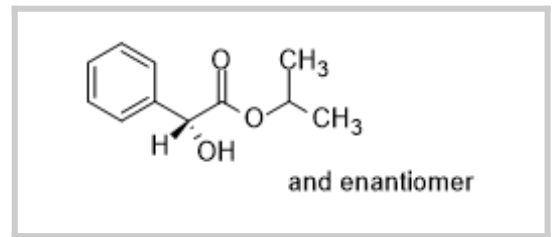
Chemical Name :
1-Methylethyl (2RS)-2-hydroxy-2-phenylacetate

CAT No. : KMP004004

CAS No. : 4118-51-8

Molecular Formula : C₁₁H₁₄O₃

Molecular Weight : 194.23



Analytical Information

Batch No. : MAN-IE-073-192

Description : Off White Solid

HPLC Purity : 99.96 %

Weight Loss By TGA : 0.34 %

% Potency : 99.62 %

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 - 0.34(Weight Loss By TGA)] x [99.96(HPLC Purity)]/100 = 99.62 %

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