

CERTIFICATE OF ANALYSIS

(Certificate No. KMP004005-01)

Release Date: 27/05/2024

Re-test Date: 26/05/2027

Pregabalin EP Impurity C

Identification

Chemical Name :

(2RS)-2-Hydroxy-2-phenylacetic acid (Mandelic acid)

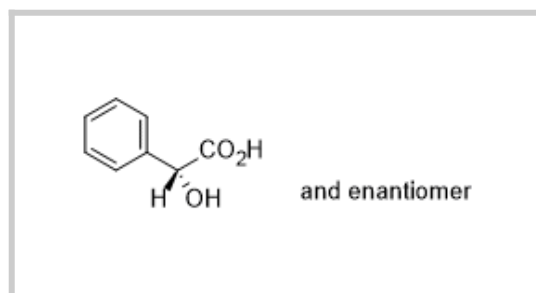
Alt. Name : Mandelic acid

CAT No. : KMP004005

CAS No. : 90-64-2

Molecular Formula : C₈H₈O₃

Molecular Weight : 152.2



Analytical Information

Batch No. : PRE-IMP-C-073-241

Solubility : ACN

Description : Off white solid

Mass : Confirm

HPLC Purity : 99.44 %

IR : Confirm

Weight Loss By TGA : 0.07 %

¹H NMR : Confirm

% Potency : 99.37 %

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 - 0.07(Weight Loss By TGA)] x [99.44(HPLC Purity)]/100 = 99.37 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/05/2024
Reviewed & Approved By	Quality Control	Jatin Patel		28/05/2024

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