

# 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)

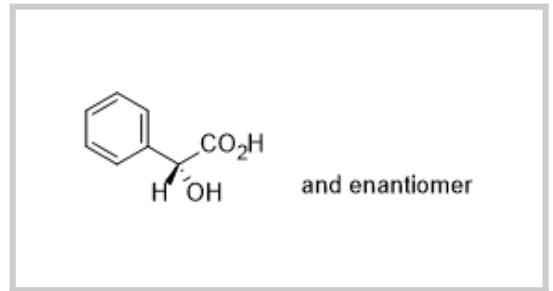
**Alt. Name** : Mandelic acid

**CAT No.** : KMP004005

**CAS No.** : 90-64-2

**Molecular Formula** : C<sub>8</sub>H<sub>8</sub>O<sub>3</sub>

**Molecular Weight** : 152.2



### Analytical Information

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

**Description** : Off white solid

**HPLC Purity** : 99.44 %

**Weight Loss By TGA** : 0.07 %

**% Potency** : 99.37 %

**Solubility** : ACN

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 0.07(Weight Loss By TGA)] x [99.44(HPLC Purity)]/100 = 99.37 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		28/05/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		28/05/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA