

# CERTIFICATE OF ANALYSIS

(Certificate No. KMP004004-01)

Release Date: 30/04/2024

Re-test Date: 29/04/2027

## Pregabalin BP Impurity D

### Identification

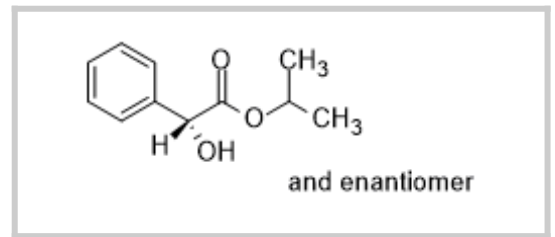
**Chemical Name :**  
1-Methylethyl (2RS)-2-hydroxy-2-phenylacetate

**CAT No. :** KMP004004

**CAS No. :** 4118-51-8

**Molecular Formula :** C<sub>11</sub>H<sub>14</sub>O<sub>3</sub>

**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

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

**Recommendation :** Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		12/07/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		12/07/2024

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