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

CH₃

and enantiomer

Analytical Information

HPLC Purity : 99.96 % **IR** : Confirm

Weight Loss By TGA : 0.34 % 1H NMR : Confirm

% Potency : 99.62 %

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