CERTIFICATE OF ANALYSIS

(Certificate No. KMP004004-01)

Release Date: 30/04/2024 **Re-test Date:** 29/04/2027

Pregabalin BP Impurity D

Identification

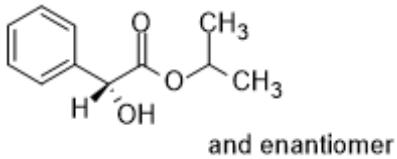
Chemical Name :
1-Methylethyl (2RS)-2-hydroxy-2-phenylacetate

CAT No. : KMP004004

CAS No. : 4118-51-8

Molecular Formula : C11H14O3

Molecular Weight : 194.23



and enantiomer

Analytical Information

Batch No.	: MAN-IE-073-192	**Solubility**	: ACN
Description	: Off White Solid	**Mass**	: Confirm
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