

CERTIFICATE OF ANALYSIS

(Certificate No. KML020013-01)

Release Date: 27/01/2023

Re-test Date: 26/01/2026

Pregabalin (R)-1-Phenylethanamine Impurity

Identification

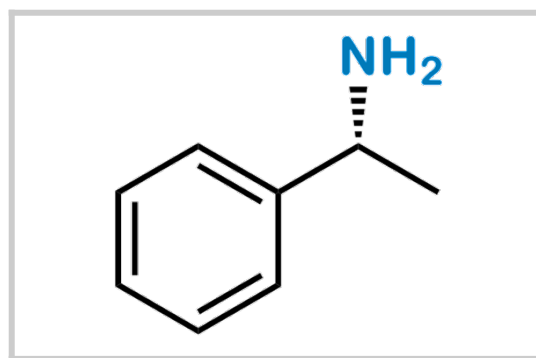
Chemical Name :
(1R)-1-Phenylethan-1-amine (as per EP)

CAT No. : KML020013

CAS No. : 3886-69-9

Molecular Formula : C₈H₁₁N

Molecular Weight : 121.2



Analytical Information

Batch No. : PRE-MBA-09-099

Description : Colorless Liquid

HPLC Purity : 99.88 %

Weight Loss By TGA : 0.31 %

% Potency : 99.57 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H 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 - 0.31(Weight Loss By TGA)] x [99.88(HPLC Purity)]/100 = 99.57 %

Remarks : COA Re-generated on 21.09.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		13/11/2024
Reviewed & Approved By	Quality Control	Jatin Patel		13/11/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA