# **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	Solubility	: Acetonitrile
Description	: Colorless Liquid	Mass	: Confirm
HPLC Purity	: 99.88 %	IR	: Confirm
Weight Loss By TGA	: 0.31 %	1H NMR	: Confirm
% Potency	: 99.57 %		

### **Additional Information**

Long Term Storage	: Store at 2-8 deg. C for long term storage
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**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, 1HNMR, IR and TGA