

CERTIFICATE OF ANALYSIS

(Certificate No. KML020012-01)

Release Date: 04/03/2025

Re-test Date: 03/03/2028

Levetiracetam EP Impurity D

Identification

Chemical Name :
(2R)-2-(2-Oxopyrrolidin-1-yl)butanamide

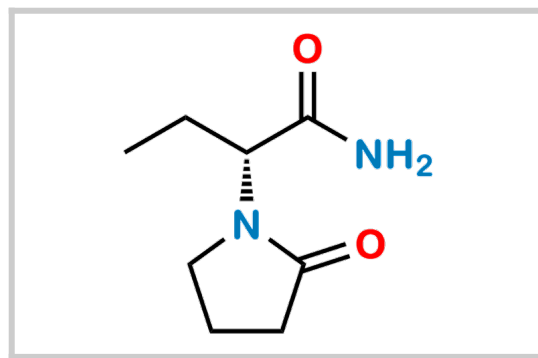
Alt. Name : (R)-Etiracetam ; Levetiracetam R-Isomer

CAT No. : KML020012

CAS No. : 103765-01-1

Molecular Formula : C₈H₁₄N₂O₂

Molecular Weight : 170.2



Analytical Information

Batch No. : L020012-091-241

Description : Off White Solid

HPLC Purity : 92.90 %

Weight Loss By TGA : 0.32 %

% Potency : 92.6 %

Solubility : ACN : Water (1:1)

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 = $[100 - 0.32(\text{Weight Loss By TGA})] \times [92.90(\text{HPLC Purity})]/100 = 92.6 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		04/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		04/03/2025

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