

# 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

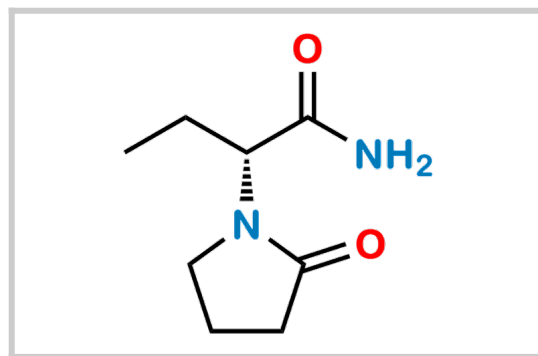
**Alt. Name** : (R)-Etiracetam ; Levetiracetam R-Isomer

**CAT No.** : KML020012

**CAS No.** : 103765-01-1

**Molecular Formula** : C<sub>8</sub>H<sub>14</sub>N<sub>2</sub>O<sub>2</sub>

**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

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C 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(Weight Loss By TGA)] x [92.90(HPLC Purity)]/100 = 92.6 %

**Recommendation** : Released

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

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA