

# CERTIFICATE OF ANALYSIS

(Certificate No. KME116025-01)

Release Date: 27/12/2024

Re-test Date: 26/12/2027

## Etodolac EP Impurity J

### Identification

**Chemical Name :**

(1R)-1,8-diethyl-1-methyl-1,3,4,9-tetrahydropyrano[3,4-b]indole (as per EP)

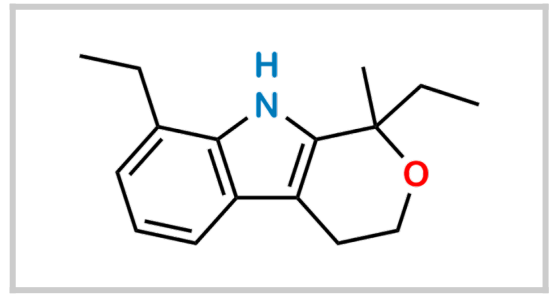
**Alt. Name** : Decarboxy Etodolac

**CAT No.** : KME116025

**CAS No.** : 115066-03-0

**Molecular Formula** : C<sub>16</sub>H<sub>21</sub>NO

**Molecular Weight** : 243.3



### Analytical Information

**Batch No.** : E116025-091-111

**Description** : Yellow Solid

**HPLC Purity** : 98.19 %

**Weight Loss By TGA** : 0.12 %

**% Potency** : 98.07 %

**Solubility** : Acetonitrile

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 0.12(Weight Loss By TGA)] x [98.19(HPLC Purity)]/100 = 98.07 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Parag Patel		27/12/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		27/12/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA