

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)

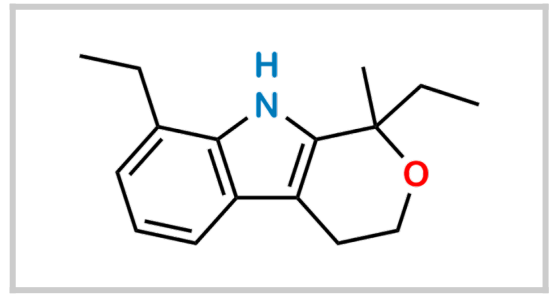
Alt. Name : Decarboxy Etodolac

CAT No. : KME116025

CAS No. : 115066-03-0

Molecular Formula : C₁₆H₂₁NO

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

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 = $[100 - 0.12(\text{Weight Loss By TGA})] \times [98.19(\text{HPLC Purity})]/100 = 98.07 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		27/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		27/12/2024

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA