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

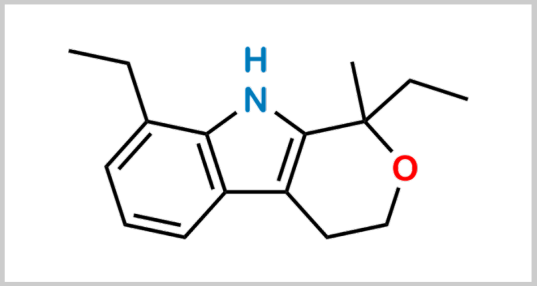
Alt. Name : Decarboxy Etodolac

CAT No. : KME116025

CAS No. : 115066-03-0

Molecular Formula : C16H21NO

Molecular Weight : 243.3



Analytical Information

Batch No.	: E116025-091-111	**Solubility**	: Acetonitrile
Description	: Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 98.19 %	**IR**	: Confirm
Weight Loss By TGA	: 0.12 %	**1H NMR**	: Confirm
% Potency	: 98.07 %		

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
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