CERTIFICATE OF ANALYSIS

(Certificate No. KME116018-01)

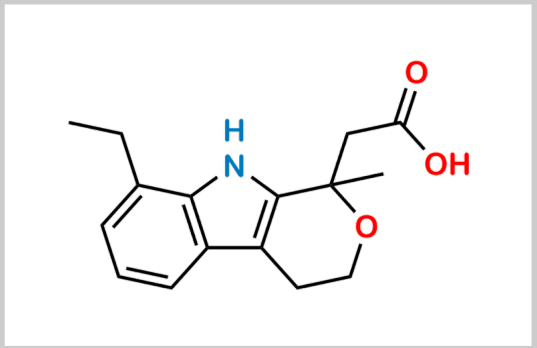
Release Date: 07/05/2025 **Re-test Date:** 06/05/2028

ETODOLAC RELATED COMPOUND A

Identification

Chemical Name :
(1RS)-8-ethyl-1-methyl-1,3,4,9-tetrahydropyrano[3,4-b]indol-1-yl]acetic acid (as per EP); (+/-)-8-Ethyl-1-methyl-1,3,4,9-tetrahydropyrano [3,4-b]-indole-1-acetic acid (as per USP)

Alt. Name	: Etodolac USP Related Compound A ; Entecavir USP Impurity I ; 1-Methyl Etodolac
CAT No.	: KME116018
CAS No.	: 109518-50-5
Molecular Formula	: C16H19NO3
Molecular Weight	: 273.3



Analytical Information

Batch No.	: E116018-102-013	**Solubility**	: Acetonitrile
Description	: White Solid	**Mass**	: Confirm
HPLC Purity	: 99.96 %	**IR**	: Confirm
Weight Loss By TGA	: 0.15 %	**1H NMR**	: Confirm
% Potency	: 99.81 %		

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 - 0.15(Weight Loss By TGA)] x [99.96(HPLC Purity)]/100 = 99.81 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		07/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		07/05/2025

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