

# 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)

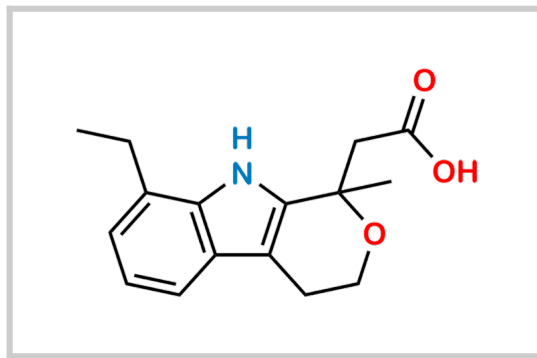
**Alt. Name** : Etodolac USP Related Compound A ;  
Entecavir USP Impurity I ; 1-Methyl  
Etodolac

**CAT No.** : KME116018

**CAS No.** : 109518-50-5

**Molecular Formula** : C<sub>16</sub>H<sub>19</sub>NO<sub>3</sub>

**Molecular Weight** : 273.3



### Analytical Information

**Batch No.** : E116018-102-013

**Description** : White Solid

**HPLC Purity** : 99.96 %

**Weight Loss By TGA** : 0.15 %

**% Potency** : 99.81 %

**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 - 0.15(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, <sup>1</sup>HNMR, IR and TGA