

# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMK001001-01)

**Release Date:** 20/02/2024

**Re-test Date:** 19/02/2027

## **Ketorolac EP Impurity H**

### **Identification**

**Chemical Name :**  
methyl 5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylate

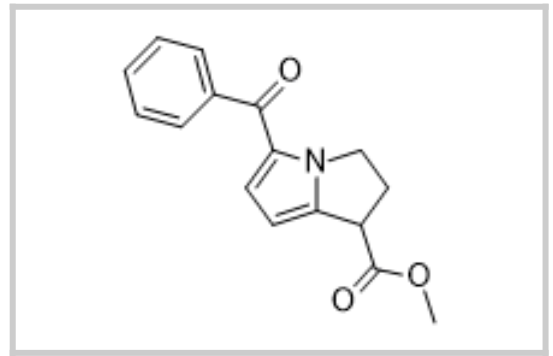
**Alt. Name** : Ketorolac Methyl Ester

**CAT No.** : KMK001001

**CAS No.** : 80965-09-9

**Molecular Formula** : C<sub>16</sub>H<sub>15</sub>NO<sub>3</sub>

**Molecular Weight** : 269.30



### **Analytical Information**

**Batch No.** : KET-EPH-073-078

**Description** : Light Orange Solid

**HPLC Purity** : 99.75 %

**Weight Loss By TGA** : 0.29 %

**% Potency** : 99.46 %

**Solubility** : ACN

**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 - 0.29(Weight Loss By TGA)] x [99.75(HPLC Purity)]/100 = 99.46 %

**Recommendation** : Released

	<b>Department</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>
<b>Prepared By</b>	Analytical	Parag Patel		20/02/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		20/02/2024

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