

# 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

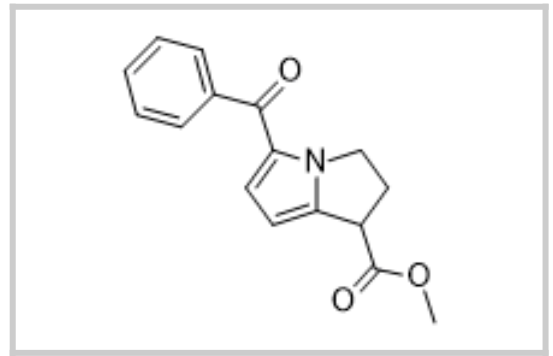
**Alt. Name :** Ketorolac Methyl Ester

**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 =**  $[100 - 0.29(\text{Weight Loss By TGA})] \times [99.75(\text{HPLC Purity})]/100 = 99.46 \%$

**Recommendation :** Released

	Department	Name	Signature	Date
<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