

# CERTIFICATE OF ANALYSIS

(Certificate No. KMK001003-01)

Release Date: 01/03/2024

Re-test Date: 28/02/2027

## Ketorolac EP Impurity D

### Identification

**Chemical Name :**

5-benzoyl-1-methoxy-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid

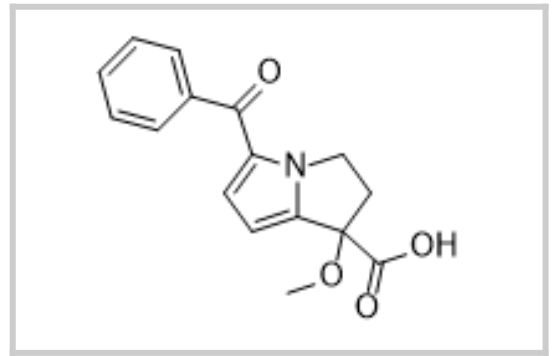
**Alt. Name** : 1-Methoxy Ketorolac , Ketorolac 1-Methoxy Impurity

**CAT No.** : KMK001003

**CAS No.** : 1391053-45-4

**Molecular Formula** : C<sub>16</sub>H<sub>15</sub>N<sub>1</sub>O<sub>4</sub>

**Molecular Weight** : 285.29



### Analytical Information

**Batch No.** : KET-EPD-073-106

**Solubility** : ACN

**Description** : Orange Hygroscopic Solid

**Mass** : Confirm

**HPLC Purity** : 97.20 %

**IR** : Confirm

**Weight Loss By TGA** : 0.67 %

**<sup>1</sup>H NMR** : Confirm

**% Potency** : 96.55 %

### 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 - 0.67(Weight Loss By TGA)] x [97.20(HPLC Purity)]/100 = 96.55 %

**Recommendation** : Released

|                                   | Department      | Name          | Signature | Date       |
|-----------------------------------|-----------------|---------------|-----------|------------|
| <b>Prepared By</b>                | Analytical      | Jignesh Patel |           | 01/03/2024 |
| <b>Reviewed &amp; Approved By</b> | Quality Control | Jatin Patel   |           | 01/03/2024 |

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