

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

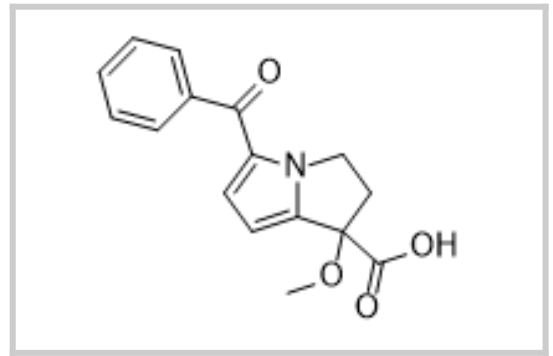
Alt. Name : 1-Methoxy Ketorolac , Ketorolac 1-Methoxy Impurity

CAT No. : KMK001003

CAS No. : 1391053-45-4

Molecular Formula : C₁₆H₁₅N₁O₄

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 %

¹H 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 |
|-----------------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 01/03/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 01/03/2024 |

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA