CERTIFICATE OF ANALYSIS

(Certificate No. KMK001003-01)

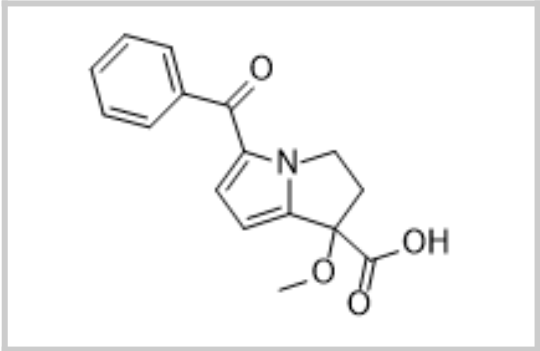
Release Date: 01/03/2024 **Re-test Date:** 28/02/2027

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	: C16H15NO4
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, 1HNMR, IR and TGA