

CERTIFICATE OF ANALYSIS

(Certificate No. KME008006-01)

Release Date: 21/09/2023

Re-test Date: 20/09/2026

Enzalutamide Acid Impurity

Identification

Chemical Name :

4-[3-[4-Cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-thioxo-1-imidazolidinyl]-2-fluoro-benzoic Acid

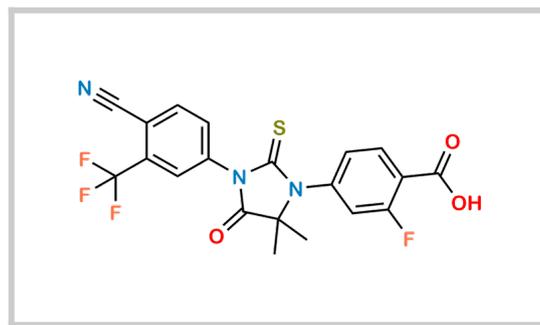
Alt. Name : Enzalutamide Carboxylic Acid Impurity;

CAT No. : KME008006

CAS No. : 1242137-15-0

Molecular Formula : C₂₀H₁₃F₄N₃O₃S

Molecular Weight : 451.4



Analytical Information

Batch No. : ENZ-ACID-045-278

Description : Off White Solid

HPLC Purity : 93.03 %

Weight Loss By TGA : 2.57 %

% Potency : 90.64 %

Solubility : ACN : Water (7:3)

Mass : Confirm

IR : Confirm

¹H 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 - 2.57(Weight Loss By TGA)] x [93.03(HPLC Purity)]/100 = 90.64 %

Remarks : COA Re-generated on 08.02.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		08/02/2025

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