

# 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

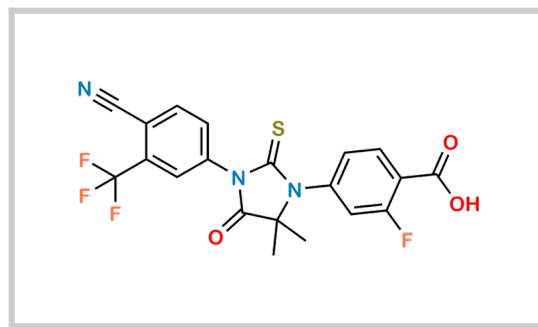
**Alt. Name** : Enzalutamide Carboxylic Acid Impurity;

**CAT No.** : KME008006

**CAS No.** : 1242137-15-0

**Molecular Formula** : C<sub>20</sub>H<sub>13</sub>F<sub>4</sub>N<sub>3</sub>O<sub>3</sub>S

**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

**<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 - 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, <sup>1</sup>H NMR, IR and TGA