

CERTIFICATE OF ANALYSIS

(Certificate No. KME008093-01)

Release Date: 23/08/2023

Re-test Date: 22/08/2026

Enzalutamide Diketo Impurity

Identification

Chemical Name :

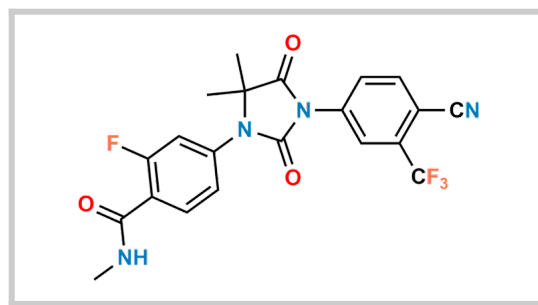
4-(3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-2,4-dioximidazolidin-1-yl)-2-fluoro-N-methylbenzamide;

CAT No. : KME008093

CAS No. : 1242137-18-3

Molecular Formula : C₂₁H₁₆F₄N₄O₃

Molecular Weight : 448.4



Analytical Information

Batch No. : ENZ-OXO-045-252

Description : Off White Solid

HPLC Purity : 97.69 %

Weight Loss By TGA : 0.10 %

% Potency : 97.59 %

Solubility : Acetonitrile

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 - 0.10(Weight Loss By TGA)] x [97.69(HPLC Purity)]/100 = 97.59 %

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