CERTIFICATE OF ANALYSIS

(Certificate No. KME008010-01)

Release Date: 16/12/2023 **Re-test Date:** 15/12/2026

Enzalutamide Impurity 1

Identification

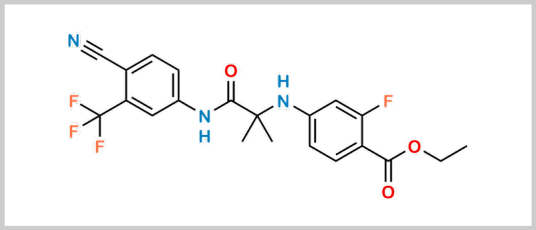
Chemical Name :
Ethyl 4-((1-((4-cyano-3-(trifluoromethyl)phenyl)amino)-2-methyl-1-oxopropan-2-yl)amino)-2-fluorobenzoate

CAT No. : KME008010

CAS No. : 2463603-98-5

Molecular Formula : C21H19F4N3O3

Molecular Weight : 437.4



Analytical Information

Batch No.	: ENZ-IMP-1-045-347	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 98.26 %	**IR**	: Confirm
Weight Loss By TGA	: 1.35 %	**1H NMR**	: Confirm
% Potency	: 96.93 %		

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 - 1.35(Weight Loss By TGA)] x [98.26(HPLC Purity)]/100 = 96.93 %
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, 1HNMR, IR and TGA