CERTIFICATE OF ANALYSIS

(Certificate No. KME008001-01)

Release Date: 25/09/2026 **Re-test Date:** 24/09/2029

Enzalutamide Impurity I

Identification

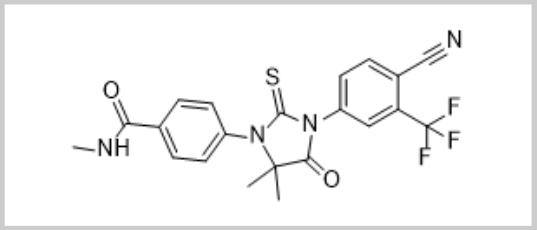
Chemical Name :
4-(3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-1-yl)-N-methylbenzamide

CAT No. : KME008001

CAS No. : 915087-16-0

Molecular Formula : C21H17F3N4O2S

Molecular Weight : 446.45



Analytical Information

Batch No.	: ENZ-DES-FLUORO-019-308	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 97.81 %	**IR**	: Confirm
Weight Loss By TGA	: 0.75 %	**1H NMR**	: Confirm
% Potency	: 97.08 %		

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 - 0.75(Weight Loss By TGA)] x [97.81(HPLC Purity)]/100 = 97.08 %
-Re-tested on 25.09.2026

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/09/2026
Reviewed & Approved By	Quality Control	Jatin Patel		25/09/2026

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA