

CERTIFICATE OF ANALYSIS

(Certificate No. KME005005-01)

Release Date: 24/05/2022

Re-test Date: 23/05/2025

Ezetimibe Ketone Impurity

Identification

Chemical Name :

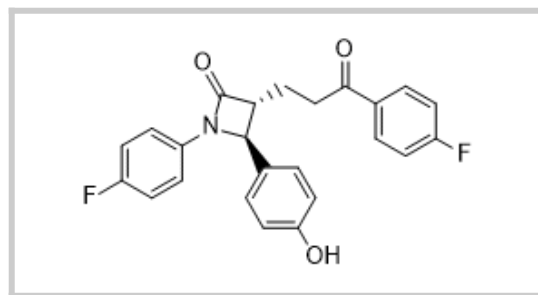
(3R,4S)-1-(4-Fluorophenyl)-3-[3-(4-fluorophenyl)-3-oxopropyl]-4-(4-hydroxyphenyl)-2-azetidinon

CAT No. : KME005005

CAS No. : 191330-56-0

Molecular Formula : C₂₄H₁₉F₂NO₃

Molecular Weight : 407.41



Analytical Information

Batch No. : EZE-KET-030-124

Description : Off White Solid

HPLC Purity : 99.77 %

Weight Loss By TGA : 0.82 %

% Potency : 98.95 %

Solubility : ACN

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 - 0.82(Weight Loss By TGA)] x [99.77(HPLC Purity)]/100 = 98.95 %

Remarks : COA Re-generated on 26.07.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		26/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		26/07/2024

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