

CERTIFICATE OF ANALYSIS

(Certificate No. KME005037-01)

Release Date: 10/07/2024

Re-test Date: 09/07/2027

Ezetimibe Cyclic Ether Impurity

Identification

Chemical Name :

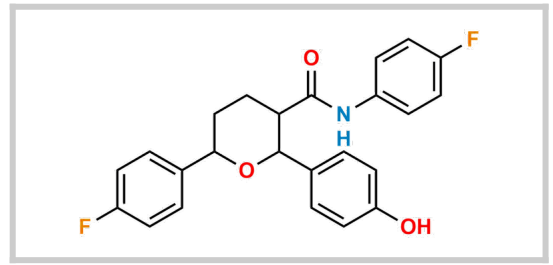
N,6-Bis(4-fluorophenyl)-2-(4-hydroxyphenyl)tetrahydro-2H-pyran-3-carboxamide

CAT No. : KME005037

CAS No. : 1050631-82-7

Molecular Formula : C₂₄H₂₁F₂NO₃

Molecular Weight : 409.4



Analytical Information

Batch No. : EZE-THP-011-089

Description : Off white solid

HPLC Purity : 93.16 %

Weight Loss By TGA : 0.59 %

% Potency : 92.61 %

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 - 0.59(Weight Loss By TGA)] x [93.16(HPLC Purity)]/100 = 92.61 %
-Re-tested on 10.07.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		18/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		18/02/2025

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