

CERTIFICATE OF ANALYSIS

(Certificate No. KML054019-01)

Release Date: 09/09/2024

Re-test Date: 08/09/2027

Lercanidipine EP Impurity C

Identification

Chemical Name :

3-[1-[(3,3-Diphenylpropyl)(methyl)amino]-2-methylpropan-2-yl] 5-methyl 2,6-dimethyl-4-(3-nitrophenyl)pyridine-3,5-dicarboxylate

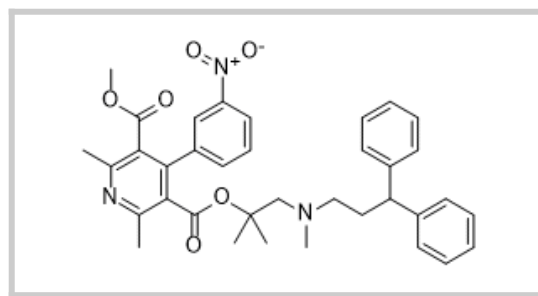
Alt. Name : Dehydro Lercanidipine

CAT No. : KML054019

CAS No. : 887769-34-8

Molecular Formula : C36H39N3O6

Molecular Weight : 609.7



Analytical Information

Batch No. : L054019-073-364

Description : Yellow Semi Solid

HPLC Purity : 99.56 %

Weight Loss By TGA : 0.53 %

% Potency : 99.03 %

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 = $[100 - 0.53(\text{Weight Loss By TGA})] \times [99.56(\text{HPLC Purity})]/100 = 99.03 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		09/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		09/09/2024

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