

# 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

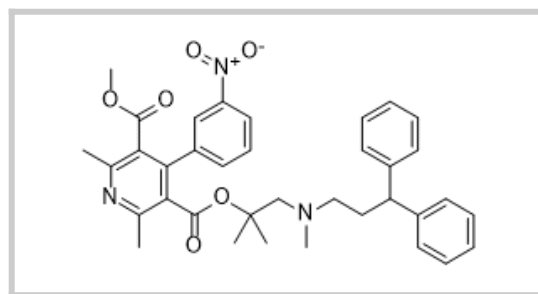
**Alt. Name** : Dehydro Lercanidipine

**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

**<sup>1</sup>H 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(Weight Loss By TGA)] x [99.56(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, <sup>1</sup>HNMR, IR and TGA