

CERTIFICATE OF ANALYSIS

(Certificate No. KMA011021-01)

Release Date: 28/02/2025

Re-test Date: 27/02/2028

Amlodipine EP Impurity B

Identification

Chemical Name :

3-Ethyl 5-methyl (4RS)-4-(2-chlorophenyl)-6-methyl-2-[[2-[[2-(methylcarbamoyl)benzoyl]amino]ethoxy]methyl]-1,4-dihydropyridine-3,5-dicarboxylate (as per EP)

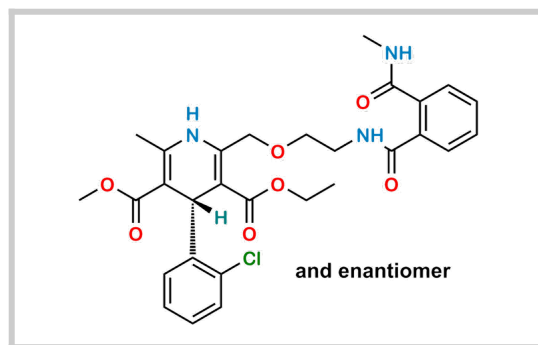
Alt. Name : Methylaminophthaloyl Amlodipine;

CAT No. : KMA011021

CAS No. : 721958-72-1

Molecular Formula : C₂₉H₃₂ClN₃O₇

Molecular Weight : 570.1



Analytical Information

Batch No. : A011021-091-235

Description : Off white solid

HPLC Purity : 99.98 %

Weight Loss By TGA : 0.74 %

% Potency : 99.24 %

Solubility : ACN : Water (1:1)

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 - 0.74(Weight Loss By TGA)] x [99.98(HPLC Purity)]/100 = 99.24 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		04/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		04/03/2025

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