

CERTIFICATE OF ANALYSIS

(Certificate No. KMA011030-01)

Release Date: 14/07/2026

Re-test Date: 13/07/2029

AMLODIPINE BESYLATE EP IMPURITY H

Identification

Chemical Name :

2-[[2-[[[(4RS)-4-(2-chlorophenyl)-3-(ethoxycarbonyl)-5-(methoxycarbonyl)-6-methyl-1,4-dihydropyridin-2-yl]methoxy]ethyl]carbamoyl]benzoic acid (as per EP)

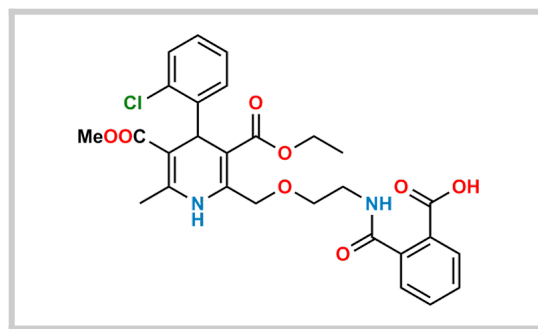
Alt. Name : 2-Carboxybenzoyl Amlodipine;

CAT No. : KMA011030

CAS No. : 318465-73-5

Molecular Formula : C₂₈H₂₉ClN₂O₈

Molecular Weight : 557.0



Analytical Information

Batch No. : A011030-136-106

Description : Off White Solid

HPLC Purity : 97.04 %

Weight Loss By TGA : 1.40 %

% Potency : 95.68 %

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 - 1.40(Weight Loss By TGA)] x [97.04(HPLC Purity)]/100 = 95.68 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		14/07/2026
Reviewed & Approved By	Quality Control	Jatin Patel		14/07/2026

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