CERTIFICATE OF ANALYSIS

(Certificate No. KMA011021-01)

Release Date: 28/02/2025 **Re-test Date:** 27/02/2028

AMLODIPINE BESYLATE 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)

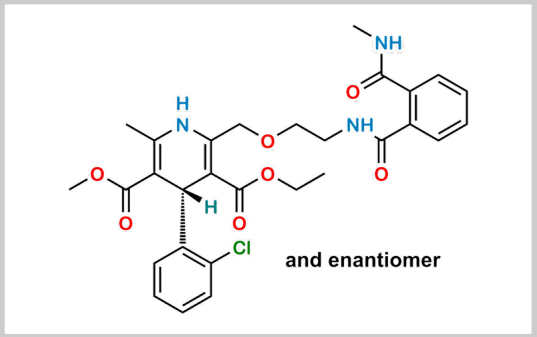
Alt. Name : Methylaminophthaloyl Amlodipine;

CAT No. : KMA011021

CAS No. : 721958-72-1

Molecular Formula : C29H32ClN3O7

Molecular Weight : 570.1



Analytical Information

Batch No.	: A011021-091-235	**Solubility**	: ACN : Water (1:1)
Description	: Off white solid	**Mass**	: Confirm
HPLC Purity	: 99.98 %	**IR**	: Confirm
Weight Loss By TGA	: 0.74 %	**1H NMR**	: Confirm
% Potency	: 99.24 %		

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		28/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		28/02/2025

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