

CERTIFICATE OF ANALYSIS

(Certificate No. KMA011026-01)

Release Date: 18/03/2025

Re-test Date: 17/03/2028

Amlodipine EP Impurity E

Identification

Chemical Name :

Diethyl 2-((2-aminoethoxy)methyl)-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzenesulfonate

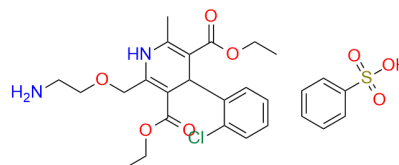
Alt. Name : Amlodipine Diethyl Ester; Amlodipine Ethyl Analog (USP)

CAT No. : KMA011026

CAS No. : Not Available

Molecular Formula : C₂₁H₂₇ClN₂O₅ : C₆H₆O₃S

Molecular Weight : 422.9 : 158.18



Analytical Information

Batch No. : AMDP-E

Solubility : DMSO

Description : Off White Solid

Mass : Confirm

HPLC Purity : 98.15 %

IR : Confirm

Weight Loss By TGA : 0.40 %

¹H NMR : Confirm

% Potency : 97.76 %

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 - 0.40(Weight Loss By TGA)] x [98.15(HPLC Purity)]/100 = 97.76 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		18/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		18/03/2025

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