

CERTIFICATE OF ANALYSIS

(Certificate No. KMA011026-02)

Release Date: 14/05/2025

Re-test Date: 13/05/2028

Amlodipine EP Impurity E

Identification

Chemical Name :

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

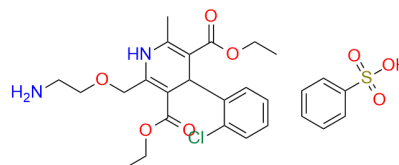
Alt. Name : Amlodipine Diethyl Ester; Amlodipine Ethyl Analog (USP)

CAT No. : KMA011026

CAS No. : Not Available

Molecular Formula : C₂₁H₂₇ClN₂O₅ : C₆H₆O₃S

Molecular Weight : 422.9 : 158.18



Analytical Information

Batch No. : A011026-102-029

Description : Light Yellow Solid

HPLC Purity : 95.55 %

Weight Loss By TGA : 0.50 %

% Potency : 95.07 %

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 - 0.50(Weight Loss By TGA)] x [95.55(HPLC Purity)]/100 = 95.07 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		15/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		15/05/2025

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