

# 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

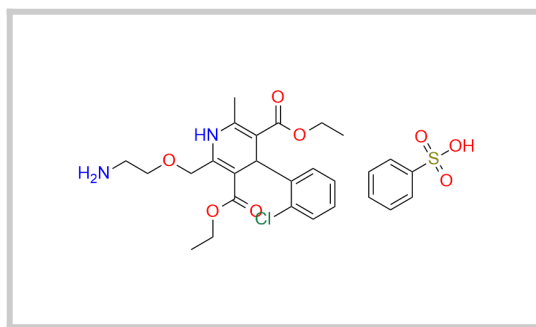
**Alt. Name** : Amlodipine Diethyl Ester; Amlodipine Ethyl Analog (USP)

**CAT No.** : KMA011026

**CAS No.** : Not Available

**Molecular Formula** : C<sub>21</sub>H<sub>27</sub>ClN<sub>2</sub>O<sub>5</sub> : C<sub>6</sub>H<sub>6</sub>O<sub>3</sub>S

**Molecular Weight** : 422.9 : 158.18



### Analytical Information

**Batch No.** : AMDP-E

**Description** : Off White Solid

**HPLC Purity** : 98.15 %

**Weight Loss By TGA** : 0.40 %

**% Potency** : 97.76 %

**Solubility** : DMSO

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 0.40(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, <sup>1</sup>H NMR, IR and TGA