

CERTIFICATE OF ANALYSIS

(Certificate No. KMA011003-02)

Release Date: 05/03/2025

Re-test Date: 04/03/2028

Amlodipine Related Compound A

Identification

Chemical Name :

3-Ethyl 5-methyl 2-((2-aminoethoxy)methyl)-4-(2-chlorophenyl)-6-methylpyridine-3,5-dicarboxylate fumarate

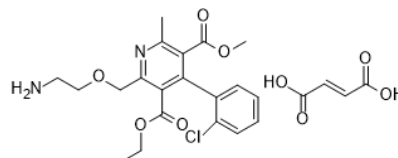
Alt. Name : Amlodipine USP Related Compound A

CAT No. : KMA011003

CAS No. : 2138811-33-1

Molecular Formula : C₂₀H₂₃ClN₂O₅ : C₄H₄O₄

Molecular Weight : 406.86 : 116.07



Analytical Information

Batch No. : A011003-091-246

Description : Off White Solid

HPLC Purity : 99.40 %

Weight Loss By TGA : 0.87 %

% Potency : 98.54 %

Solubility : ACN : Water (1:1)

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 - 0.87(Weight Loss By TGA)] x [99.40(HPLC Purity)]/100 = 98.54 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		01/12/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/12/2025

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