

CERTIFICATE OF ANALYSIS

(Certificate No. KMA011003-01)

Release Date: 24/08/2022

Re-test Date: 23/08/2025

Amlodipine Related Compound A

Identification

Chemical Name :

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

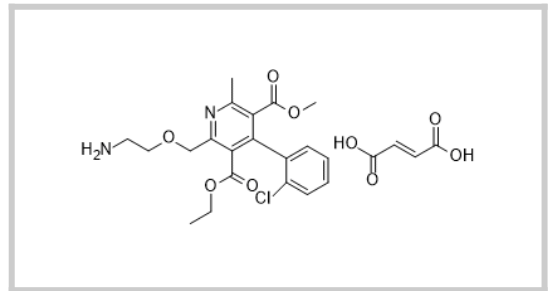
Alt. Name : Amlodipine USP Related Compound A

CAT No. : KMA011003

CAS No. : 2138811-33-1

Molecular Formula : C₂₀H₂₃ClN₂O₅ : C₄H₄O₄

Molecular Weight : 406.86 : 116.07



Analytical Information

Batch No. : AML-RC-A-030-262

Description : White Solid

HPLC Purity : 95.34 %

Weight Loss By TGA : 2.05 %

% Potency : 93.39 %

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 = $[100 - 2.05(\text{Weight Loss By TGA})] \times [95.34(\text{HPLC Purity})]/100 = 93.39 \%$

Remarks : COA Re-generated on 12.06.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		12/06/2024
Reviewed & Approved By	Quality Control	Jatin Patel		12/06/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA