

CERTIFICATE OF ANALYSIS

(Certificate No. KMA011004-01)

Release Date: 05/08/2024

Re-test Date: 04/08/2027

Amlodipine EP Impurity A

Identification

Chemical Name :

4-(2-Chlorophenyl)-2-[[2-(1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)ethoxy]methyl]-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylic Acid 3-Ethyl 5-Methyl Ester

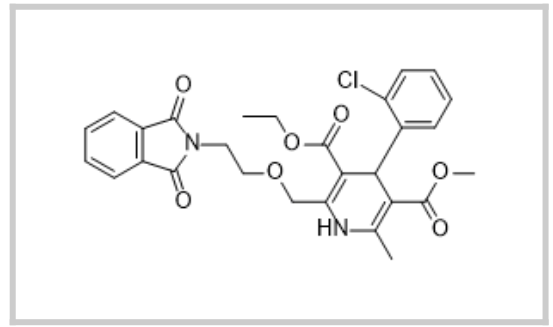
Alt. Name : Amlodipine USP Related Compound D

CAT No. : KMA011004

CAS No. : 88150-62-3

Molecular Formula : C₂₈H₂₇ClN₂O₇

Molecular Weight : 538.98



Analytical Information

Batch No. : AMD-01

Description : Off White Solid

HPLC Purity : 96.51 %

Weight Loss By TGA : 1.02 %

% Potency : 95.53 %

Solubility : ACN

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 - 1.02(Weight Loss By TGA)] x [96.51(HPLC Purity)]/100 = 95.53 %

-Re-tested on 05.08.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		09/08/2024
Reviewed & Approved By	Quality Control	Jatin Patel		09/08/2024

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