CERTIFICATE OF ANALYSIS

(Certificate No. KMA011004-02)

Release Date: 27/02/2025 **Re-test Date:** 26/02/2028

AMLODIPINE BESYLATE 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

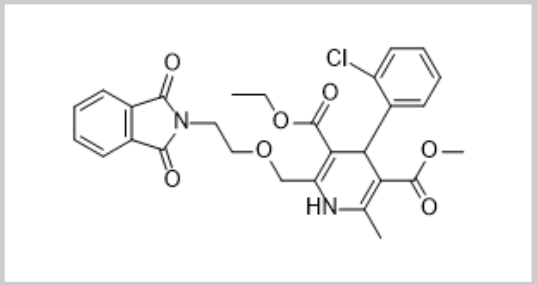
Alt. Name : Amlodipine USP Related Compound D

CAT No. : KMA011004

CAS No. : 88150-62-3

Molecular Formula : C28H27ClN2O7

Molecular Weight : 538.98



Analytical Information

Batch No. : A011004-091-232

Description : Off white solid

HPLC Purity : 99.42 %

Weight Loss By TGA : 1.10 %

% Potency : 98.33 %

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 - 1.10(Weight Loss By TGA)] x [99.42(HPLC Purity)]/100 = 98.33 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		27/02/2025

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