

CERTIFICATE OF ANALYSIS

(Certificate No. KMA011032-01)

Release Date: 24/10/2024

Re-test Date: 23/10/2027

Amlodipine Glucose + Galactose adduct Impurity

Identification

Chemical Name :

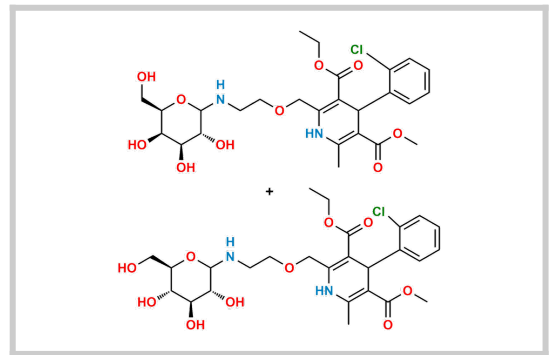
3-ethyl 5-methyl 4-(2-chlorophenyl)-6-methyl-2-((2-(((3R,4S,5R,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydro-2H-pyran-2-yl)amino)ethoxy)methyl)-1,4-dihydropyridine-3,5-dicarboxylate compound with 3-ethyl 5-methyl 4-(2-chlorophenyl)-6-methyl-2-((2-(((3R,4S,5S,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydro-2H-pyran-2-yl)amino)ethoxy)methyl)-1,4-dihydropyridine-3,5-dicarboxylate (1:1)

CAT No. : KMA011032

CAS No. : Not Available

Molecular Formula : C₂₆H₃₅ClN₂O₁₀

Molecular Weight : 571.0



Analytical Information

Batch No. : A011032-073-418

Description : Light Yellow Solid

HPLC Purity : 92.13 %

Weight Loss By TGA : 1.41 %

% Potency : 90.83 %

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 = $[100 - 1.41(\text{Weight Loss By TGA})] \times [92.13(\text{HPLC Purity})]/100 = 90.83 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		27/10/2024

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