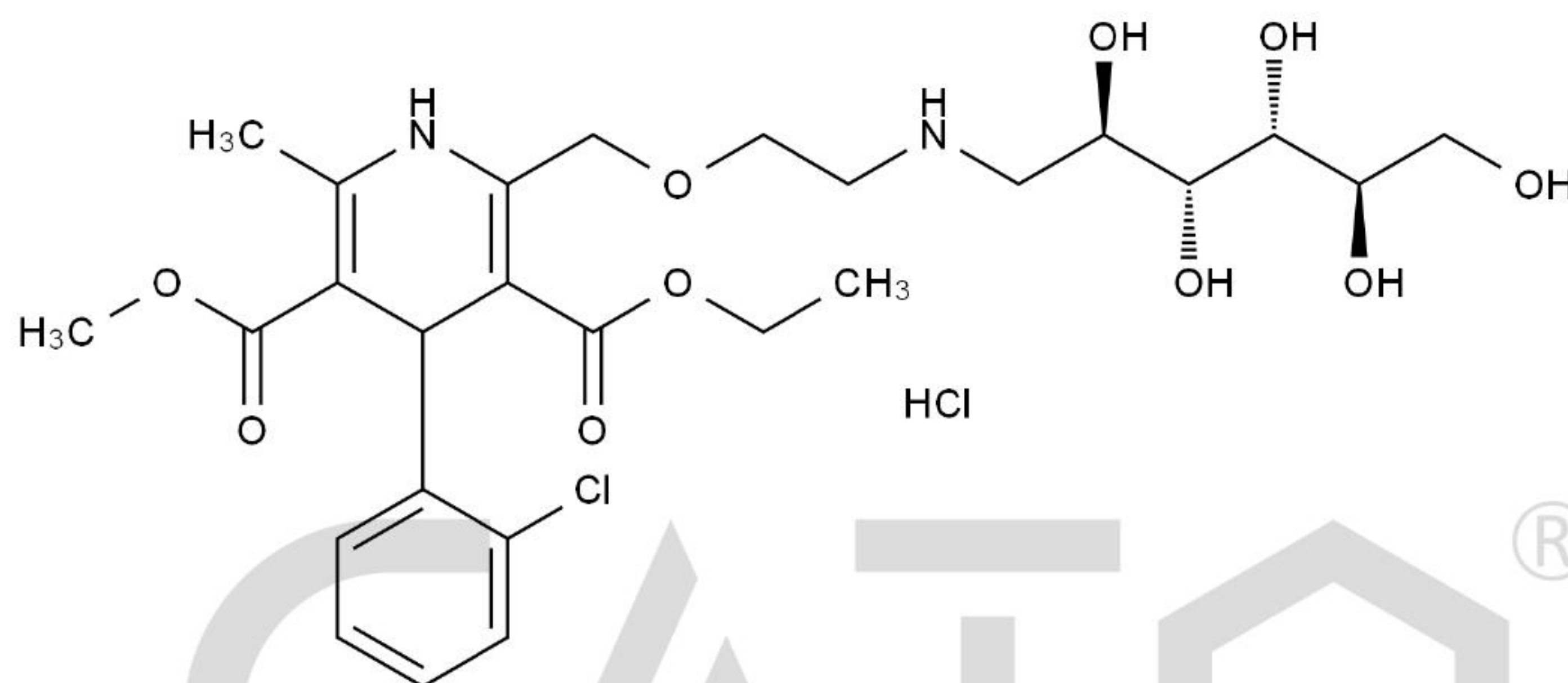


Certificate of Analysis

Reference Material

Product Name:	Amlodipine Mannitol Adduct HCl	Catalogue Number:	C4X-109570
Chemical Name:	N/A	Lot Number:	0729-RD-0007
CAS Number:	N/A	Expiry Date:	Jun 23, 2024
Molecular Formula:	C ₂₆ H ₃₇ ClN ₂ O ₁₀ HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	573.03 36.46		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	95.4956%
Water Content	Karl Fischer	6.1%
Residual Solvents	NMR	0.2% n-hexane
Assay		89.5%

Comment:

- The compound contains 3.3% Amlodipine Impurity 66 according to its HPLC and LC-MS.
- The calculation of the 100% method follows the formula:

$$\text{Assay (\%)} = (100\% - \text{Water Content} - \text{Residual Solvents}) * \text{Purity HPLC (\%)} / 100\%$$
 Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Hinlam

Reviewed by:

Cady

Aporoved by General manager:

David

Date: Jun 28, 2021

Date: Aug 02, 2022

Date: Aug 02, 2022

