

Certificate of Analysis

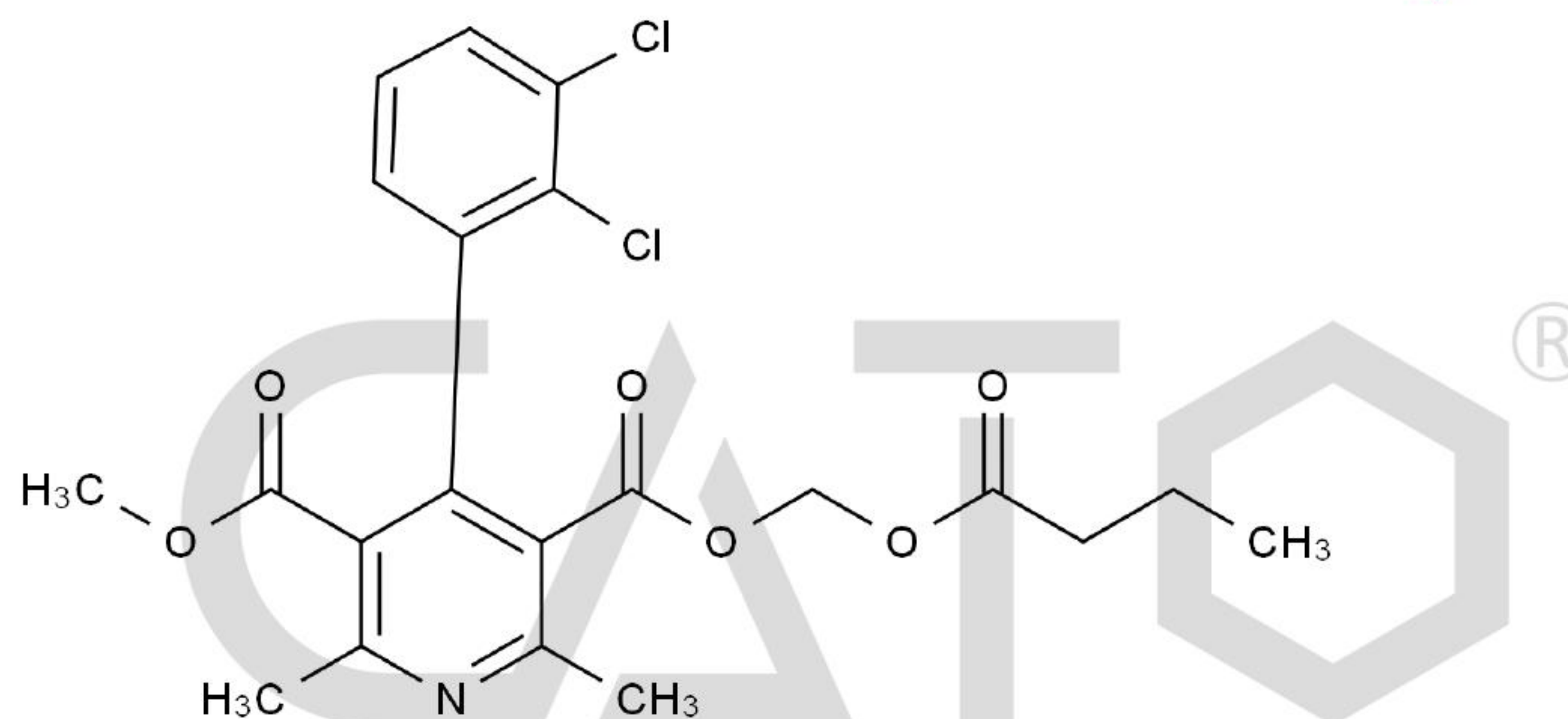
Reference Material & Standard

Product Name:	Clevipine butyrate Impurity 4	Catalogue Number:	C4X-10154
Synonyms:	N/A	Lot Number:	0701-RH-0046
CAS Number:	188649-48-1	Expiry Date:	Nov 04, 2029
Molecular Formula:	C ₂₁ H ₂₁ Cl ₂ NO ₆	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	454.30	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Oil
Identification	LCMS&IR&UV&CNMR&HNMR	Confirmed
Purity	HPLC	99.922%
Water Content	Karl Fischer	0.45%
Residual Solvents	NMR	0.51% acetonitrile
Assay		99.0%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$\text{Assay (\%)} = (100\% - \text{Water Content} - \text{Residual Solvents}) * \text{Purity HPLC (\%)} / 100\%$

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Jul 02, 2026

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