

Certificate of Analysis

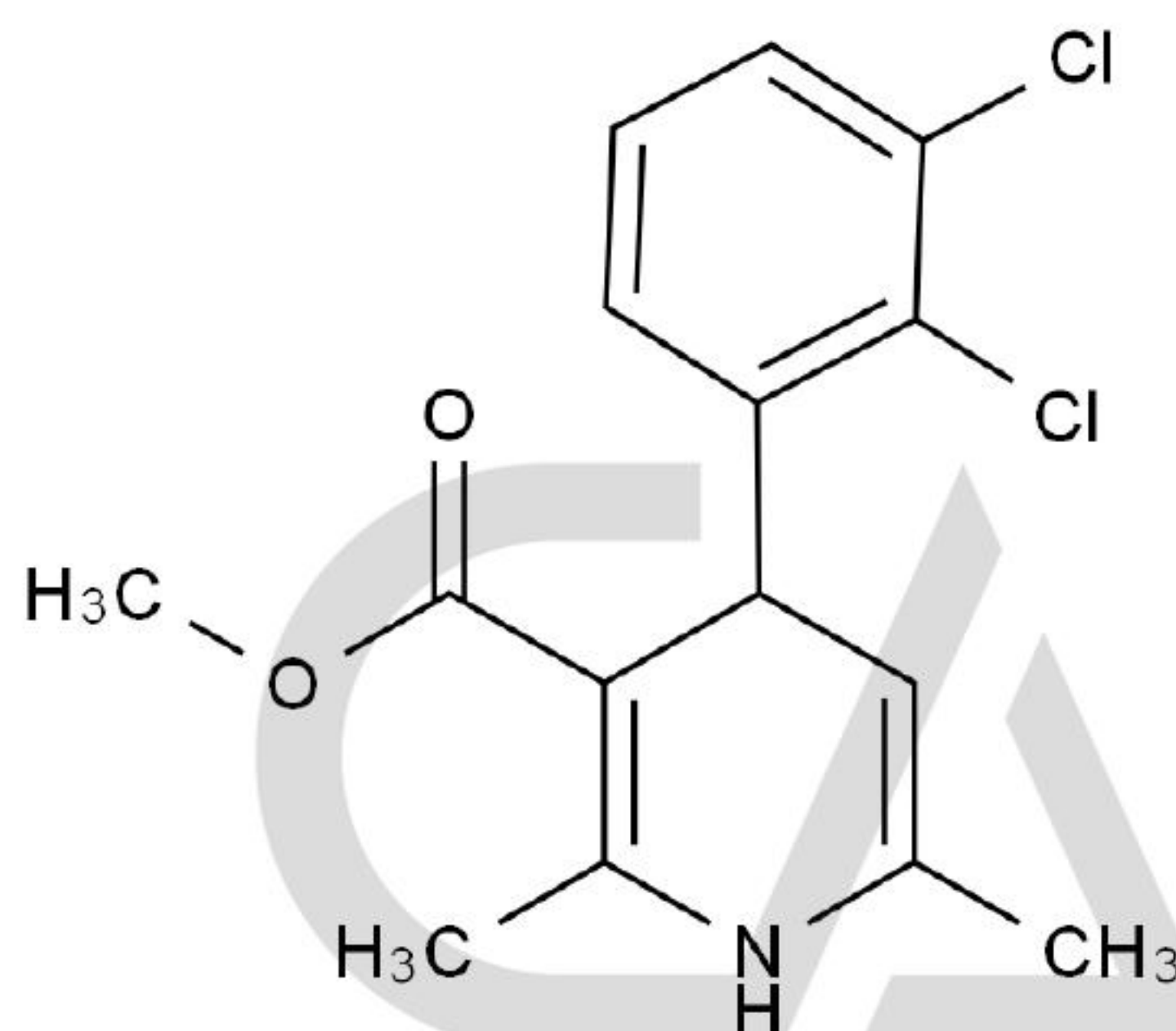
Reference Material & Standard

Product Name:	Clevipidine Butyrate impurity 19	Catalogue Number:	C4X-101519
Synonyms:	N/A	Lot Number:	0514-RH-0066
CAS Number:	253597-20-5	Expiry Date:	Mar 01, 2030
Molecular Formula:	C ₁₅ H ₁₅ Cl ₂ NO ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	312.19	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&IR&UV&CNMR&HNMR	Confirmed
Purity	HPLC	99.846%
Water Content	Karl Fischer	0.44%
Residual Solvents	NMR	0.34% ethyl acetate and 2.71% cyclohexane
Assay		96.4%

Comment:

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

Assay (%) = (100% - Water Content - Residual Solvents) * 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: May 26, 2026

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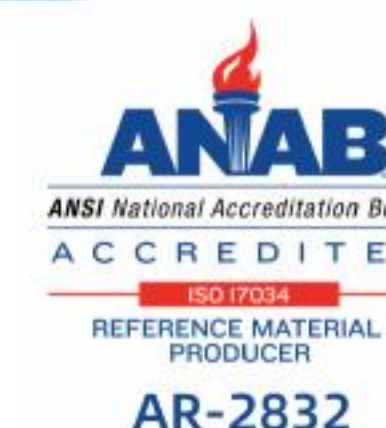
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