

Certificate of Analysis

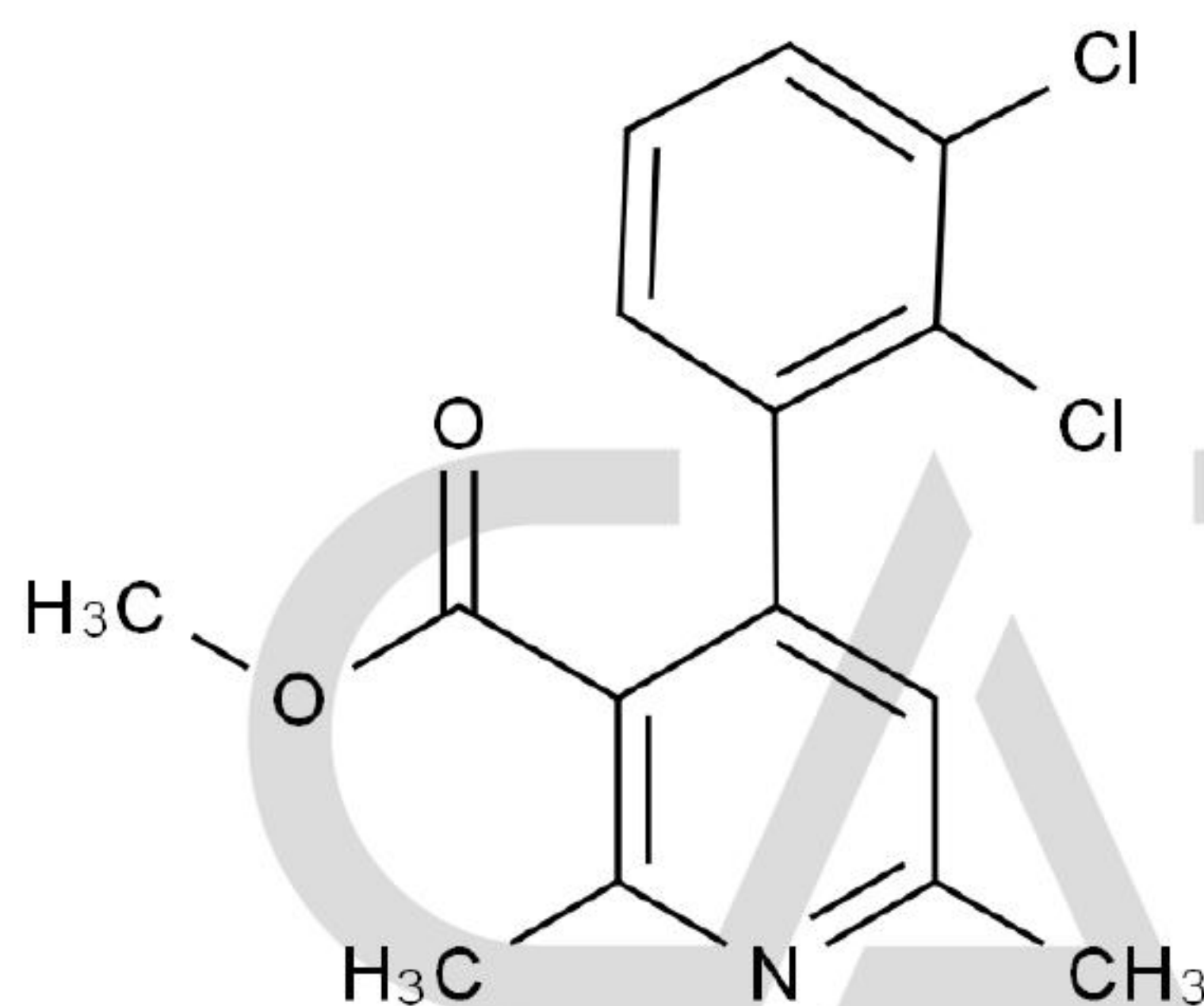
Reference Material & Standard

Product Name:	Clevipidine Butyrate impurity 18	Catalogue Number:	C4X-101518
Synonyms:	N/A	Lot Number:	1107-RG-0015
CAS Number:	105383-68-4	Expiry Date:	Oct 10, 2028
Molecular Formula:	C ₁₅ H ₁₃ Cl ₂ NO ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	310.18	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	HRMS&IR&UV&CNMR&HNMR	Confirmed
Purity	HPLC	99.987%
Water Content	Karl Fischer	0.36%
Residual Solvents	NMR	1.19% dichloromethane
Assay		98.4%

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:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Nov 13, 2025

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Add: 3rd Floor, Building B, No.179, Guangpu Rd East, Huangpu District, Guangzhou, China

Tel: +86-20-81960175

Email: supports@cato-chem.com

Web: <https://www.cato-chem.com>

