

Certificate of Analysis

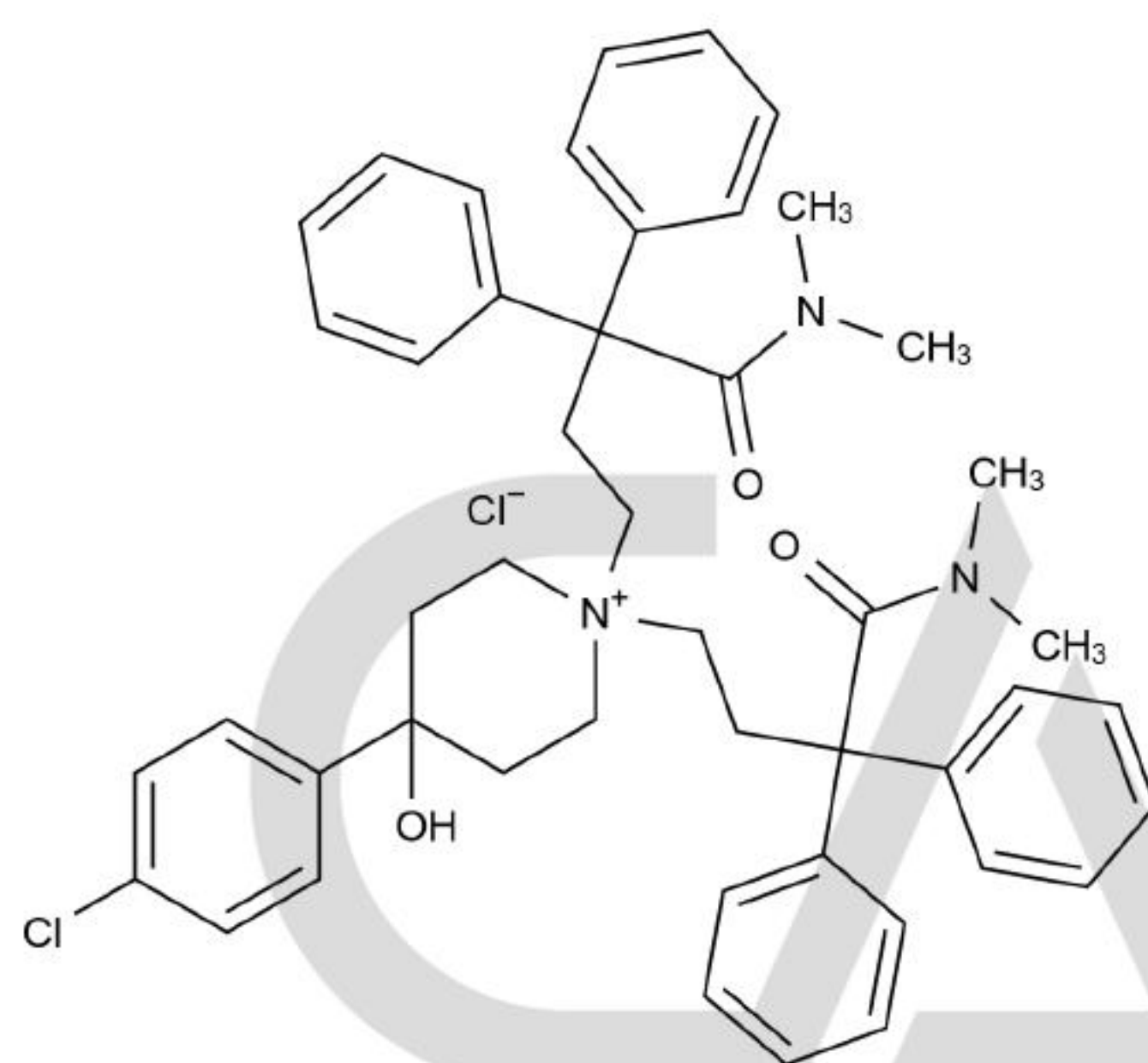
Reference Material & Standard

Product Name:	Loperamide EP Impurity B Chloride	Catalogue Number:	C4X-17882
Synonyms:	N/A	Lot Number:	1212-RD-0058
CAS Number:	N/A	Expiry Date:	May 26, 2025
Molecular Formula:	C ₄₇ H ₅₃ ClN ₃ O ₃ Cl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	743.40 35.45	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.9300%
Water Content	Karl Fischer	3.0%
Residual Solvents	NMR	Not detected in NMR
Assay		96.9%

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:

Nacy

Reviewed by:

Debia

Approved by General Manager:

David

Date: May 27, 2022

Date: Dec 23, 2022

Date: Dec 23, 2022



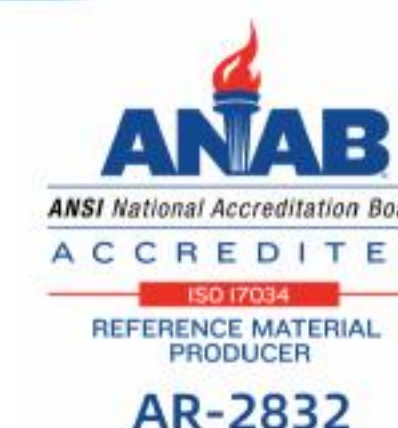
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