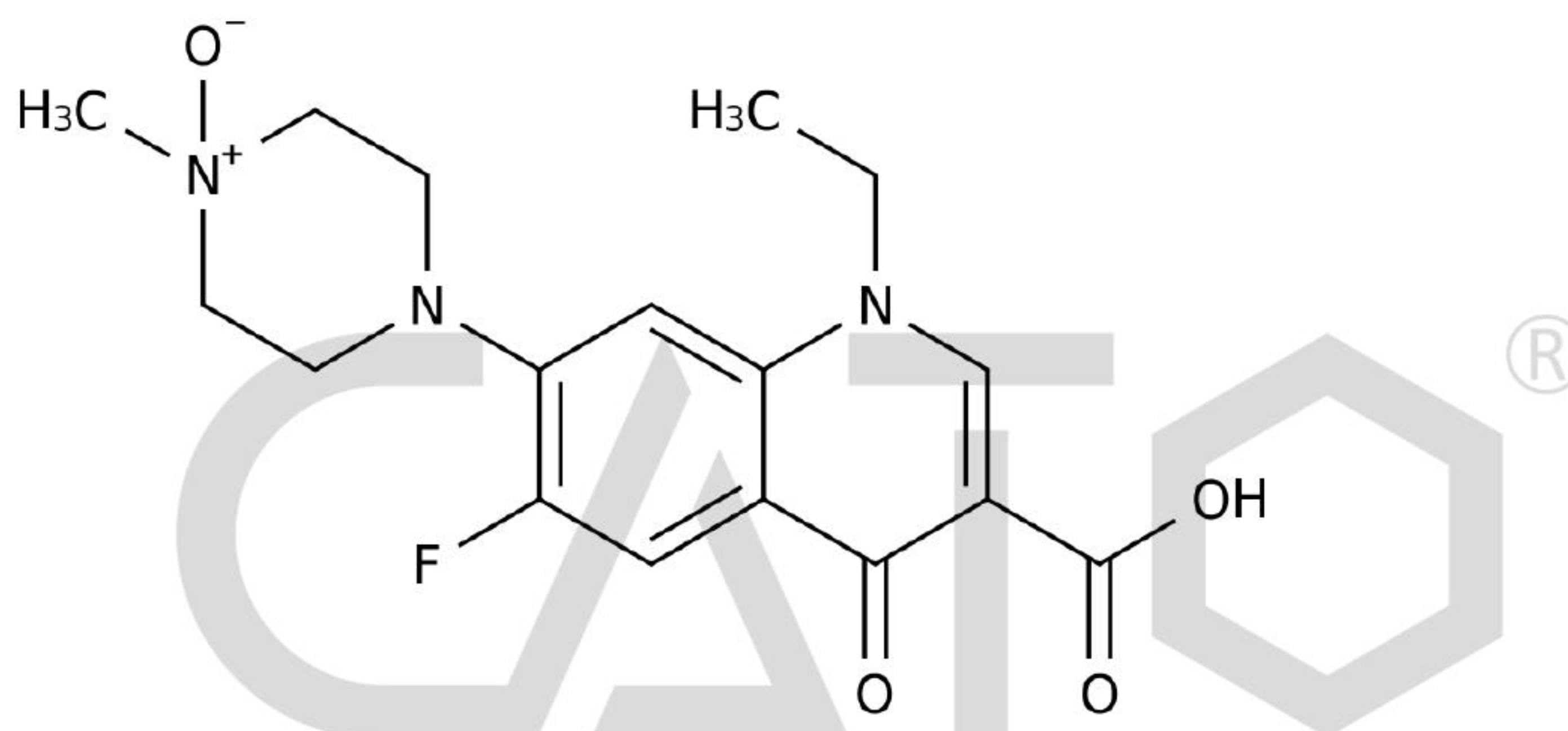


Certificate of Analysis

Reference Material & Standard

Product Name:	Pefloxacin Mesilate Dihydrate EP Impurity D	Catalogue Number:	C4X-23335
Synonyms:	N/A	Lot Number:	0827-RC-0021
CAS Number:	85145-21-7	Expiry Date:	Sep 20, 2022
Molecular Formula:	C ₁₇ H ₂₀ FN ₃ O ₄	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	349.36	Shipping Condition:	Shipping at Room Temperature

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.7018%
Water Content	Karl Fischer	3.8%
Residual Solvents	NMR	1.3% methanol
Assay		94.6%

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:

Debia

Reviewed by:

Cady

Approved by General Manager:

David

Date: Aug 27, 2021

Date: Aug 27, 2021

Date: Aug 27, 2021

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