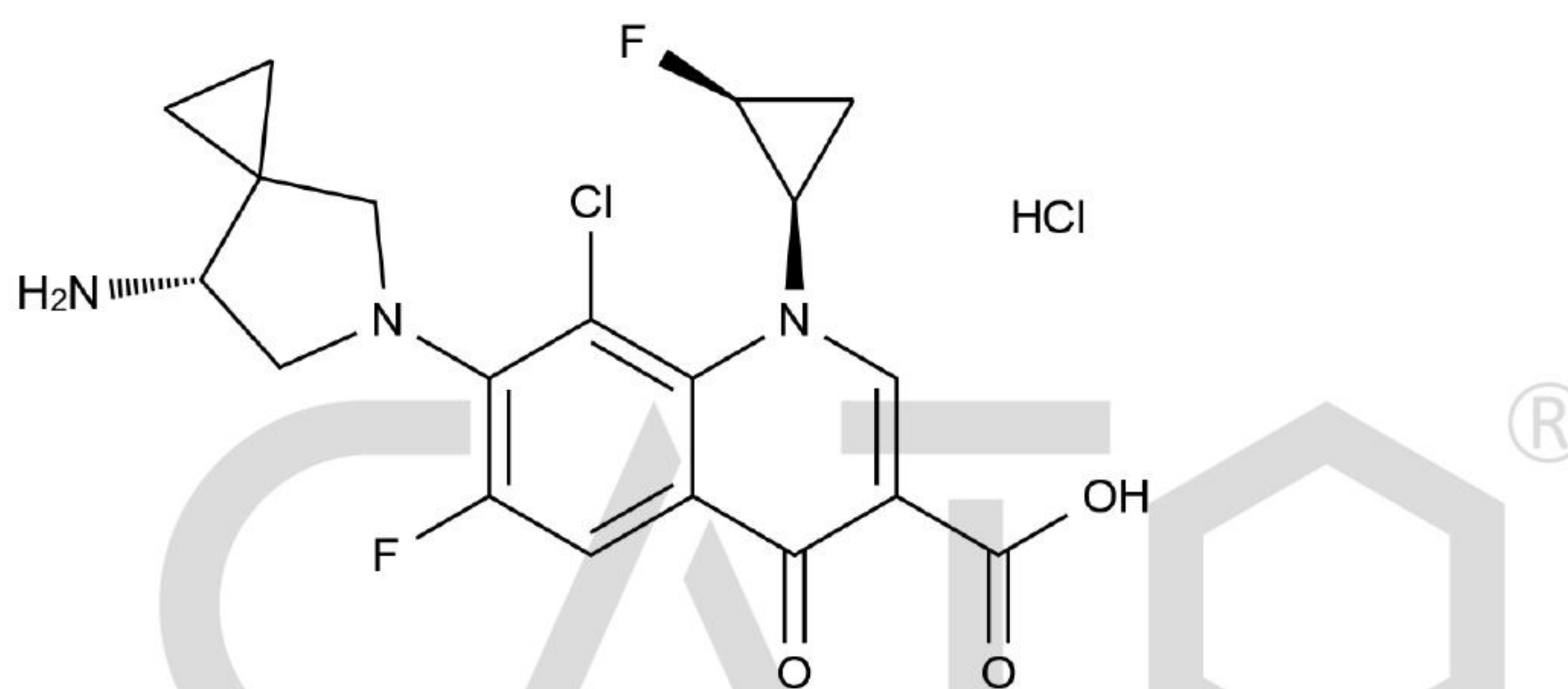


Certificate of Analysis

Reference Material & Standard

Product Name:	Sitafloxacin Isomer Impurity 9(RRS)Hydrochloride	Catalogue Number:	C4X-115551
Synonyms:	N/A	Lot Number:	1203-RF-0071
CAS Number:	127254-10-8(Free Base)	Expiry Date:	Feb 19, 2026
Molecular Formula:	C ₁₉ H ₁₈ ClF ₂ N ₃ O ₃ HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	409.81 36.46		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Solid
Identification	LCMS&CNMR&HNMR	Confirmed
Purity	HPLC	99.7801%
Water Content	Karl Fischer	0.33%
Residual Solvents	NMR	Not detected in NMR
Assay		99.5%

Comment:

The calculation of the 100% 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: Dec 04, 2024

Date: Dec 04, 2024

Date: Dec 04, 2024

