

Certificate of Analysis

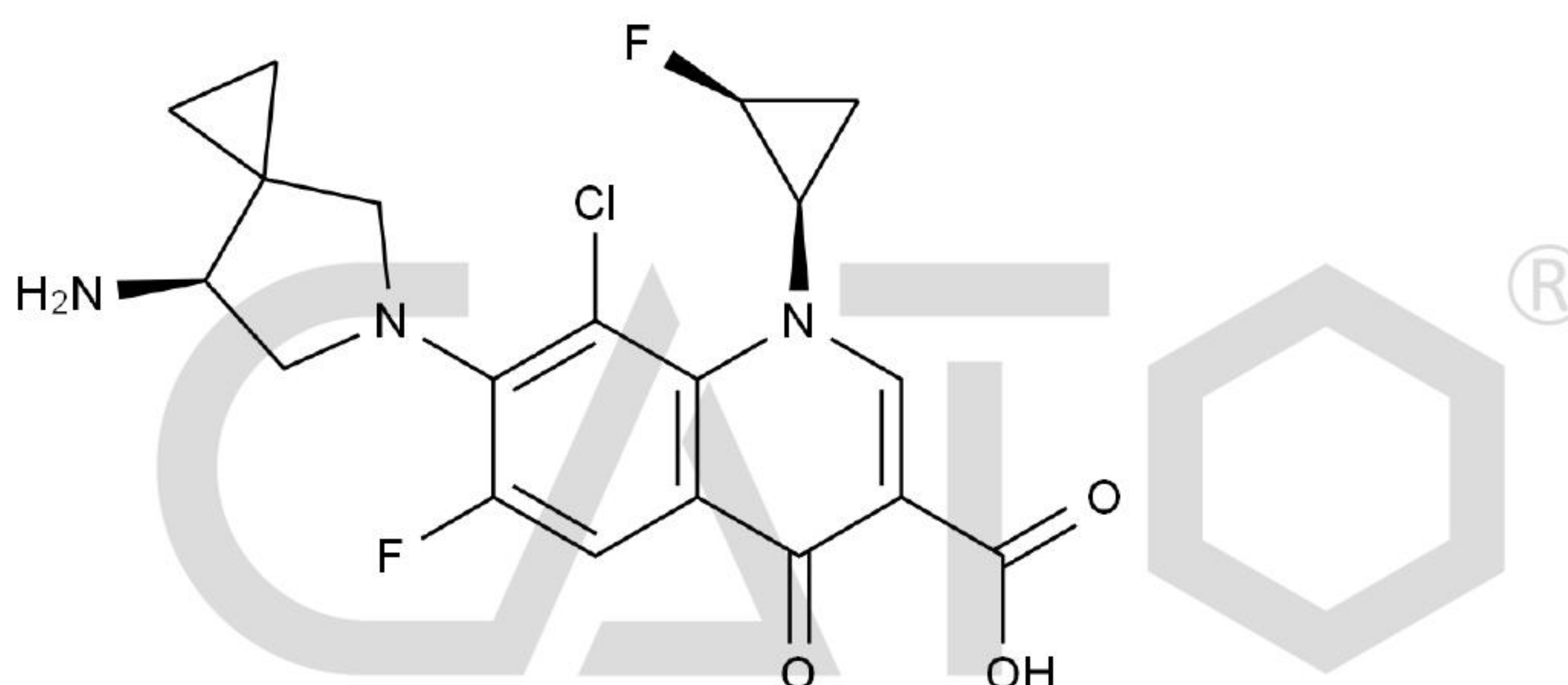
Reference Material & Standard

Product Name:	Sitafloxacin	Catalogue Number:	CCAD303173
Synonyms:	N/A	Lot Number:	1017-RG-0053
CAS Number:	127254-12-0	Expiry Date:	Oct 20, 2029
Molecular Formula:	C ₁₉ H ₁₈ ClF ₂ N ₃ O ₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	409.81		

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Loss On Drying	TGA	6.4690%
Assay		93.5%
Uncertainty		±0.7%

Comment:

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

$$\text{Assay (\%)} = (100\% - \text{Loss On Drying}) * \text{Purity HPLC (\%)} / 100\%$$

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

2. The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

Prepared by:

Nice

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Oct 21, 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>

