

Certificate of Analysis

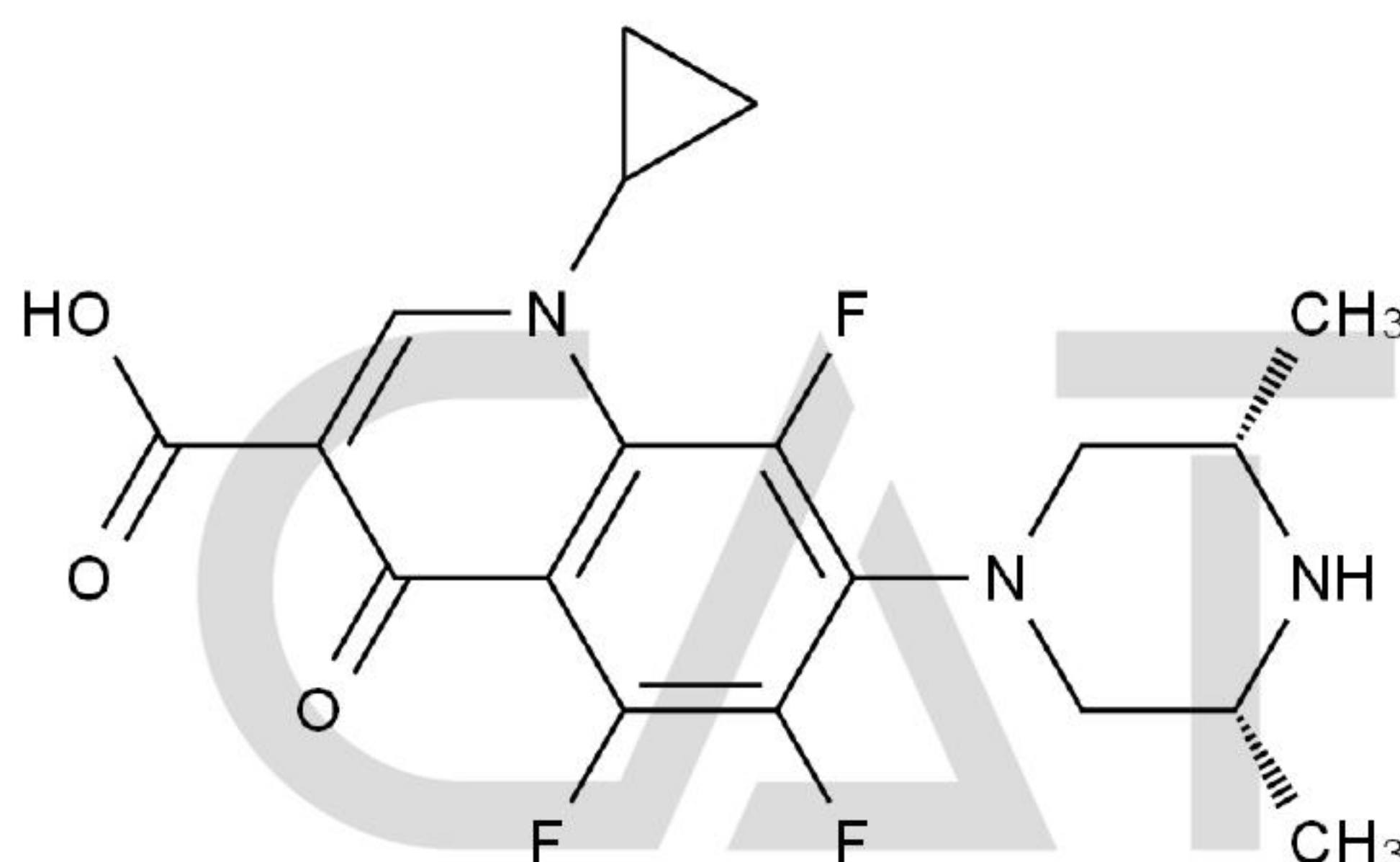
Reference Material & Standard

Product Name:	Orbifloxacin	Catalogue Number:	CCAD300341
Synonyms:	N/A	Lot Number:	0909-RF-0016
CAS Number:	113617-63-3	Expiry Date:	Sep 17, 2028
Molecular Formula:	C ₁₉ H ₂₀ F ₃ N ₃ O ₃	Storage:	Room Temp Protected from light and Sealed
Molecular Weight:	395.38	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Light Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Residue on Ignition	TGA	0.0440%
Loss on Drying	TGA	1.4048%
Assay		98.6%
Uncertainty		±2.0%

Comment:

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

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

Residue on Ignition and Loss on Drying are 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:

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Date: Oct 11, 2024

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