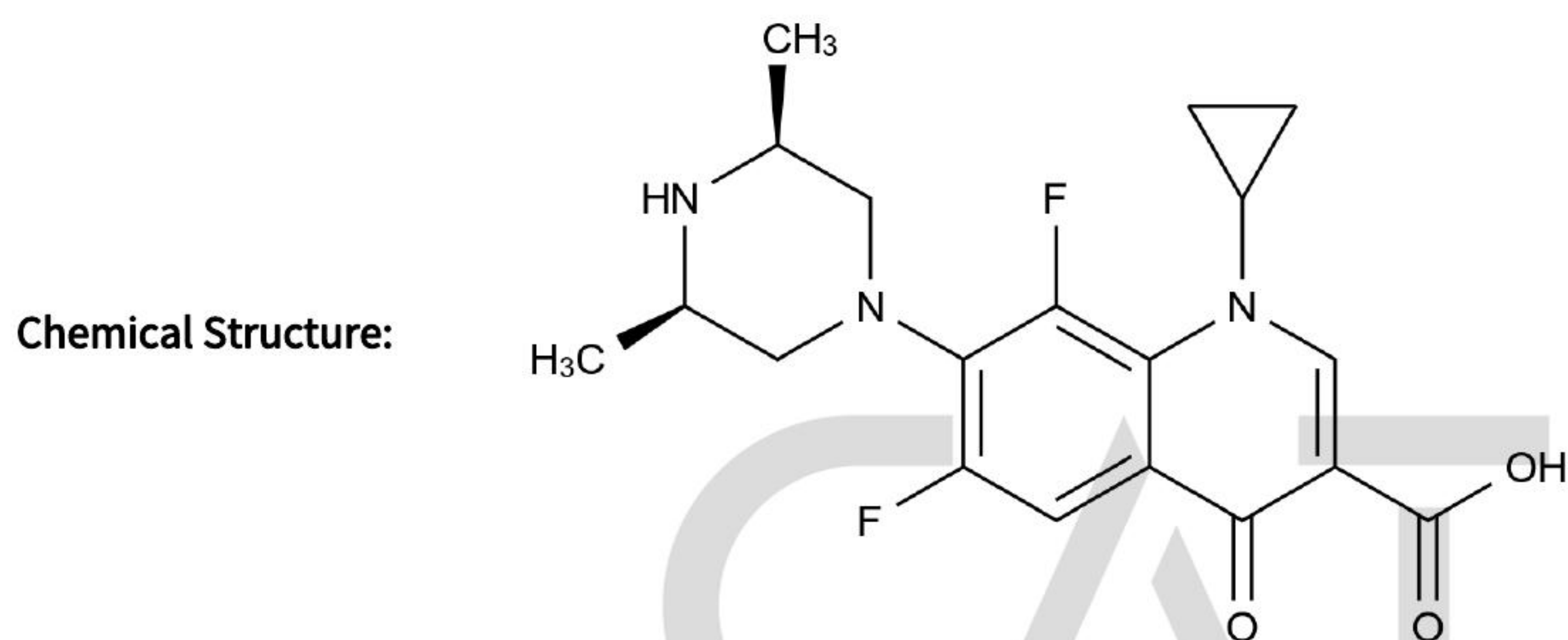


Certificate of Analysis

Reference Material & Standard

Product Name:	Orbifloxacin EP Impurity C	Catalogue Number:	C4X-25677
Synonyms:	N/A	Lot Number:	0124-RF-0016
CAS Number:	126457-99-6	Expiry Date:	Jan 17, 2027
Molecular Formula:	C ₁₉ H ₂₁ F ₂ N ₃ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	377.39		



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.2148%
Water Content	Karl Fischer	2.90%
Residual Solvents	NMR	0.4% methanol
Assay		95.9%

Comment:

The calculation of the 100% 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:

Lily

Reviewed by:

Hin Lam

Aproved by General Manager:

David

Date: Jan 25, 2024

Date: Jan 26, 2024

Date: Jan 26, 2024

