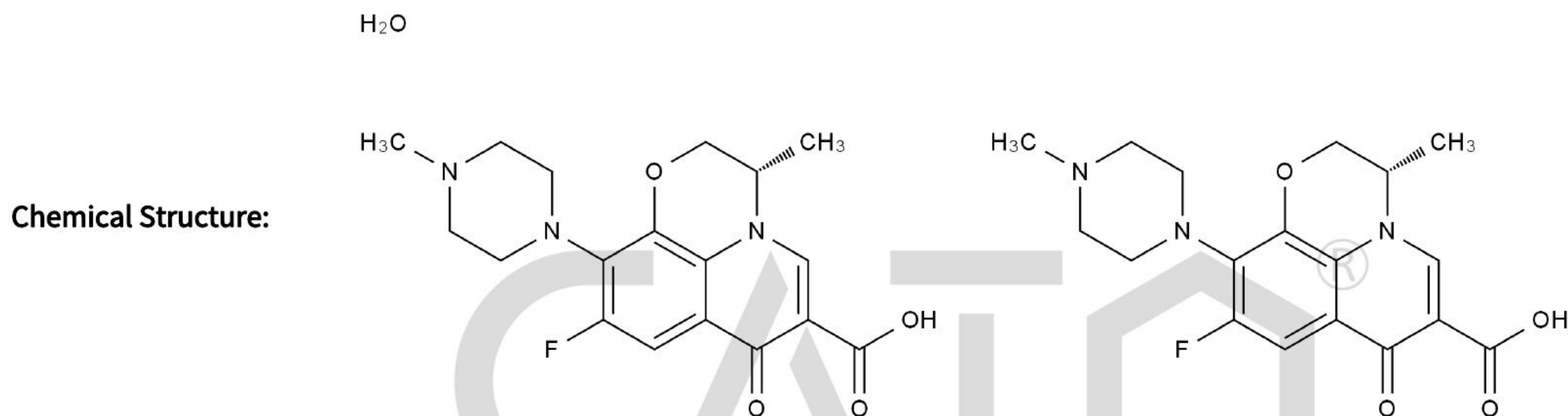


Certificate of Analysis

Reference Material & Standard

Product Name:	Levofloxacin Hemihydrate	Catalogue Number:	CCAD301220
Synonyms:	N/A	Lot Number:	0704-RF-0040
CAS Number:	138199-71-0	Expiry Date:	Jul 03, 2028
Molecular Formula:	2*C18H20FN3O4 H2O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	2*361.37 18.02	Warning:	



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.910%
Water Content	Karl Fischer	2.3401%
Assay		97.6%
Uncertainty		±2.0%

Comment:

1. The calculation of the 100% method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Water Content) * Purity HPLC (%) / 100%

Water Content 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:

Lisa

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Jul 04, 2024

Date: Jul 04, 2024

Date: Jul 04, 2024

