Application Note
Pharma

SCHMIDT HAENSCH

Ofloxacin Enantiomeric Composition Control

Monitoring Ofloxacin Enantiomeric Composition with Polarimetry

Ofloxacin is a widely used synthetic antibiotic belonging to the class of second-generation fluoroquinolones. It is applied in the treatment of bacterial infections and is available in various formulations, including:

- Oral and intravenous medications
- Ophthalmic (eye drops) and otic (ear drops) applications

Due to its broad-spectrum antibacterial activity, Ofloxacin plays an important role in both systemic and localized therapies.

Ofloxacin and Enantiomeric Composition
Ofloxacin is a chiral compound, meaning it exists in two mirror-image forms (enantiomers):

- Levofloxacin (S-enantiomer): biologically active component
- Dextrofloxacin (R-enantiomer): significantly less active

Commercial Ofloxacin is a racemic mixture, containing 50% of each enantiomer. However, the pharmacological effect is primarily determined by the active enantiomer. Enantiomers have identical chemical composition but differ in how they interact with biological systems.

This can lead to:
- Different therapeutic effects
- Different side effects
- Variations in pharmacokinetics

Therefore, precise control of enantiomeric composition is critical in pharmaceutical production.

Why Monitoring is Essential
Pharmacopoeial specifications define narrow optical rotation limits for Ofloxacin, but the exact requirement depends on the referenced standard. The USP–NF Ofloxacin monograph refers to Specific rotation, with an acceptance range of +1° to –1° for a 10 mg/mL test solution in chloroform.

The European Pharmacopoeia Ofloxacin monograph 01/2011:1455 specifies Optical rotation, with an acceptance range of –0.10° to +0.10° using a methanol / methylene chloride sample preparation. This tight specification reflects the sensitivity of the measurement to even small changes in enantiomeric composition.

Without sufficient analytical precision, manufacturers risk:
- Incorrect enantiomer ratios
- Reduced therapeutic effectiveness
- Increased risk of adverse effects
- Batch rejection and regulatory non-compliance

Given that many pharmaceutical solutions are measured at low concentrations, even small measurement errors can lead to significant deviations in calculated results.

Polarimetry is a well-established method for analyzing chiral substances such as Ofloxacin. It measures the optical rotation of polarized light passing through a sample. The relationship between optical rotation and concentration is described by Biot's Law, which allows calculation of the specific rotation, a characteristic property of the substance.

This enables:
- Determination of enantiomeric composition
- Verification of identity and purity
- Compliance with pharmacopeial standards

Because optical rotation directly reflects the presence and ratio of enantiomers, polarimetry is a fast, reliable and non-distructive tool for routine quality control.

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Solution from SCHMIDT + HAENSCH

Using the SCHMIDT + HAENSCH VariPol Polarimeter provides a highly precise method for determining the optical rotation of pharmaceutical substances such as Ofloxacin. The system enables fast and reliable measurement of specific rotation, ensuring accurate control of enantiomeric composition and compliance with pharmacopeial standards. The VariPol allows measurements under defined conditions of concentration, temperature, and wavelength for direct comparison with USP requirements. In combination with the Aquisys3 software, it offers secure data management, full traceability, and compliance with regulations such as 21 CFR Part 11, while supporting efficient workflows. This integrated solution ensures reliable quality control, and guarantees consistent pharmaceutical product quality.

VariPol
Modular Polarimeter

Product type	Product	ID-N°
Polarimeter	VariPol Modular Polarimeter	**31100**
Accessories	VariPol Tube Flow Through, 100 mm	**100000**
Accessories	VariTouch Display	**16700**
Accessories	Quartz control plate	**18940**

Advantages

- Accurate determination of enantiomeric composition
- Compliance with pharmacopeial standards (USP)
- Reliable quality control of chiral pharmaceuticals
- Reduction of batch rejection rates
- Fast and reproducible measurements
- 21 CFR Part 11 compliant
- Non-destructive by design

Typical industries

- Quality control of fluoroquinolone antibiotics
- Enantiomeric analysis of chiral drugs
- Raw material inspection
- Final product verification
- Pharmaceutical R&D