

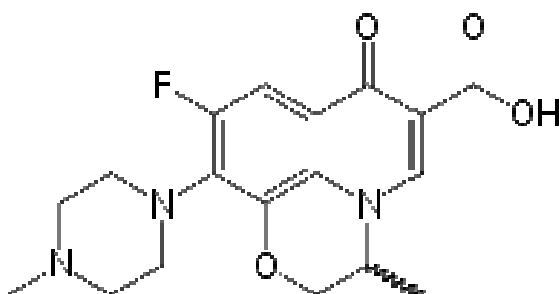
Below is an example of why Polarimeters with accuracy of  $\pm 0.02$  and  $\pm 0.01$  accuracy / precision polarimeters **are not suitable** for pharmaceutical applications.

Please review the USP monograph for the material Ofloxacin.

Ofloxacin is a synthetic chemotherapeutic antibiotic of the fluoroquinolone drug class considered to be a second-generation fluoroquinolone. Ofloxacin is sold under a wide variety of brand names as well as generic drug equivalents, for oral and intravenous administration. Ofloxacin is also available for topical use, as eye drops and ear drops (marketed as Ocuflax and Floxin Otic respectively in the United States).

Ofloxacin is a racemic mixture, which consists of 50% levofloxacin (the biologically active component) and 50% of its "mirror image" or enantiomer dextroflaxacin. When levofloxacin disks were not available in early clinical trials, a 5-pg ofloxacin disk was substituted. Like other quinolones, ofloxacin has been associated with a significant number of serious adverse drug reactions, such as tendon damage (including spontaneous tendon ruptures) and peripheral neuropathy (which may be irreversible); such reactions may manifest long after therapy had been completed, and, in severe cases, may result in life-long disabilities. Ofloxacin has also been associated with severe psychiatric adverse reactions.

## Ofloxacin



<b>Systematic (IUPAC) name</b>	(RS)-7-fluoro-2-methyl-6-(4-methylpiperazin-1-yl)-10-oxo-4-oxa-1-azatricyclo[7.3.1.0 <sup>5,13</sup> ]trideca-5(13),6,8,11-tetraene-11-carboxylic acid
<b>Clinical data</b>	Floxin, Ocuflax
<b>Trade names</b>	monograph
<b>AHFS/Drugs.com</b>	a691005
<b>MedlinePlus</b>	C(US)
<b>Pregnancy cat.</b>	Px-only (US)
<b>Legal status</b>	Oral, IV, topical (eye drops and ear drops)
<b>Routes</b>	

**Pharmacokinetic data**

Bioavailability	85% - 95%
Protein binding	32%
Half-life	8-9 hours
Identifiers CAS number	82419-36-1
ATC code	J01MA01 ,S01AX11, S02AA16
PubChem	CID 4583
DrugBank	APRD00502
ChemSpider	4422
UNII	A4P49JAZ9H
KEGG	D00453
ChEBI	CHEBI:7731
ChEMBL	CHEMBL4
Synonyms	(±)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid

**Chemical data**

Formula	C18H20FN3O4
Mol. mass	361.368 g/mol
SMILES	eMolecules & PubChem
InChI	

Ofloxacin must have a specific rotation between +1° and -1° at a concentration of 10mg per ml.

Biot's Law:

$$[\alpha]_{\lambda}^T = \frac{\alpha_{\lambda}^T}{c \times l}$$

$[\alpha]$	=	specific rotation
$l$	=	optical pathlength in dm
$\alpha$	=	optical rotation
$T$	=	temperature
$\lambda$	=	wavelength
$c$	=	concentration in g/100ml

The UNIPOL L has an precision of  $\pm 0.01^\circ$  optical rotation. Below is how its relative accuracy affects a hypothetical Ofloxacin sample:

$$[\alpha]_{\lambda}^T \text{ (Specific Rotation)} = \frac{\pm 0.01}{(1)(0.01)} \text{ (UNIPOL L)}$$

$\leftarrow 10\text{mg/ml} = 0.01\text{g/ml} = 1\text{g}/100\text{ml} = 1\% = 0.01$

**Specific Rotation Error =  $\pm 1.0$**

You cannot successfully inspect a pharmaceutical (such as Ofloxacin) having a Specific Rotation between +1 and  $\pm 1$  and a 1% concentration, which is quite common for most pharmaceuticals, with an instrument that has an accuracy of  $\pm 1.0$  in Specific Rotation.

The Unipol L 1000 has an precision of 0.005 for Optical Rotations of  $1^\circ$  Arc for a total unknown of  $\pm 0.005$  under the same conditions:

$$[\alpha]_{\lambda}^T \text{ (Specific Rotation)} = \frac{\pm 0.005}{(1)(0.01)} \text{ (UNIPOL L 1000)}$$

**Specific Rotation Error =  $\pm 0.5$**

USP Ofloxacin

Specific rotation <782S>: between +1° and -1°

Test solution: 10g per ml, in chloroform