

PRODUCTO: OFLOXACINA

ITEMS	SPECIFICATIONS
CHARACTERISTICS	A pale yellow or bright yellow crystalline powder
IDENTIFICATION	a) IR spectra b) UV spectra
LOSS ON DRYING	≤0.2%
RESIDUE ON IGNITION	≤0.1%
HEAVY METALS	≤0.001%
SPECIFIC ROTATION	-1° ~ +1°
ARSENIC	≤1 μg/g
RESIDUE SOLVENTS a) Methanol b) Ethanol	≤0.005% ≤0.05%
PURITY TEST (HPLC) ➤ Individual impurity ➤ Total impurities	≤0.3% ≤0.5%
BACTERIAL ENDOTOXINS	<0.75 EU/mg
MICROBIAL LIMIT ➤ Total bacterial count ➤ Mould and yeast count ➤ Escherichia coli	≤1000 cfu/g ≤100 cfu/g Undetected
ASSAY	98.5% ~101.5%