

Method of Analysis: **USP 46**

<i>Tests</i>	<i>Standard</i>	<i>Results</i>
<i>Description & Solubility</i>	<i>Faintly yellowish to light yellow crystals. Sparingly soluble in water. Highly soluble in acetic acid and in methanol, very slightly soluble in dichloromethane, practically insoluble in acetone, in acetonitrile, in ethyl acetate, in hexane, and in methylene chloride.</i>	Conforms
<i>Identification</i>	<i>A. IR</i>	Conforms
	<i>B. HPLC</i>	Conforms
	<i>C. Chloride</i>	Conforms
<i>Residue on ignition</i>	<i>Not more than 0.1%.</i>	0.0371%
<i>Organic impurity</i>	<i>Ciprofloxacin ethylenediamine analog</i> <i>Not more than 0.2%</i>	0.0281%
	<i>Fluoroquinolonic acid</i> <i>Not more than 0.2%</i>	0.1001%
	<i>Individual unspecified impurity</i> <i>Not more than 0.2%</i>	0.0502%
	<i>Total impurity *</i> <i>Not more than 0.5%</i>	0.1139%
<i>Water (by KF)</i>	<i>4.70 % --- 6.70 %</i>	5.75%
<i>pH</i>	<i>3.0 --- 4.5</i>	3.74
<i>Assay (by HPLC)</i>	<i>98.0 % --- 102.0 % (on the anhydrous basis)</i>	99.94%
<i>Residual solvents</i>	<i>Methanol ≤ 3000 ppm</i>	1221 ppm
	<i>1-Butanol ≤ 5000 ppm</i>	Not detected
<i>Packaging and storage</i>	<i>Preserve in tight, light-resistant containers. Store at ≤25°C, excursions permitted between 15° and 30°.</i>	