

**RAWPHARMA BIZ PVT LTD**  
**1101-CITY CENTER-2**  
**SCIENCE CITY ROAD, SOLA**  
**AHMEDABAD, 380060**  
**GUJARAT, INDIA**

**CERTIFICATE OF ANALYSIS**

<b>Product Name</b>	<b>Levofloxacin Hemihydrate</b>
<b>Grade</b>	<b>IP</b>

TEST	SPECIFICATIONS	RESULTS
Description	A yellow white to yellow powder	A yellowish white powder
Solubility	Sparingly soluble in acetic acid glacial, slightly soluble in methanol, sparingly soluble in chloroform	Complies
Identification (By IR)	The infra-red absorbance spectrum obtained from the sample should be concordant with spectrum obtained with that Levofloxacin RS/WS	Complies
Heavy Metals (In ppm)	Not more than 20 ppm	Less than 20 ppm
Water (%w/w)	Between 2.0 to 3.0	2.4
Chromatographic Purity (% Area by HPLC) <ul style="list-style-type: none"> <li>N-Desmethyl Levofloxacin</li> <li>Diamine derivative</li> <li>Levofloxacin N-oxide</li> <li>D-Isomer</li> <li>9- Desfluoro Levofloxacin</li> <li>Single maximum impurity</li> <li>Total Impurities</li> </ul>	Not more than 0.3  Not more than 0.3 Not more than 0.3 Not more than 0.8 Not more than 0.3  Not more than 0.1  Not more than 0.5	Not detected  Not detected Not detected 0.23 Not detected  0.08  0.13
Sulphated Ash	Not more than 0.2	0.05
Assay (% W/W, on dried basis, by Potentiometrically)	Not less than 98.0 and not more than 102.0 of C <sub>18</sub> H <sub>20</sub> FN <sub>3</sub> O <sub>4</sub> /2H <sub>2</sub> O	99.6
Residual Solvent (By GC-HS) <ul style="list-style-type: none"> <li>Methanol</li> <li>Dimethyl Sulphoxide</li> </ul>	Not more than 3000ppm Not more than 890ppm	512 Not detected