

**PRODUCT: FLUCONAZOLE**

<b>ITEMS</b>	<b>SPECIFICATIONS</b>
<b>DESCRIPTION</b>	White or almost white crystalline powder
<b>SOLUBILITY</b>	Freely soluble in methanol, soluble in alcohol and in acetone, sparingly soluble in isopropanol and in chloroform, slightly soluble in water and very slightly soluble in toluene
<b>APPEARANCE OF SOLUTION</b>	5% w/v solution in methanol should be clear and colourless
<b>IDENTIFICATION</b> a) <b>IR</b>  b) <b>UV</b>	Determine by Infrared absorption spectrophotometry compare the spectrum with the obtained with fluconazole RS or with the reference spectrum of fluconazole  When examined in the range 200 nm to 350 nm a 0.025% w/v solution in methanol shows absorption maxima at about 266 nm and 261 nm.
<b>LOSS ON DRYING</b>	NMT 0.50%
<b>SULPHATED ASH</b>	NMT 0.10%
<b>IRON TEST</b>	20 ppm

<p><b>RELATED COMPOUNDS BY HPLC</b></p> <ul style="list-style-type: none"> <li>➤ <b>Impurity A</b></li> <li>➤ <b>Impurity about RRT 0.6</b></li> <li>➤ <b>Impurity B</b></li> <li>➤ <b>Impurity C</b></li> <li>➤ <b>Any single maximum unknown impurity</b></li> <li>➤ <b>Total other impurity</b></li> <li>➤ <b>Total impurities</b></li> </ul>	<p>NMT 0.20%</p> <p>NMT 1.00%</p> <p>NMT 0.10%</p> <p>NMT 0.20%</p> <p>NMT 0.10%</p> <p>NMT 0.30%</p> <p>NMT 1.50%</p>
<p><b>ASSAY (on anhydrous basis)</b></p>	<p>98.00%~102.00% w/w</p>
<p><b>RESIDUAL SOLVENTS</b></p> <ul style="list-style-type: none"> <li>a) <b>Methylene chloride</b></li> <li>b) <b>Ethyl acetate</b></li> <li>c) <b>Toluene</b></li> <li>d) <b>Methanol</b></li> <li>e) <b>Acetone</b></li> <li>f) <b>IPA</b></li> </ul>	<p>NMT 500 ppm</p> <p>NMT 1000 ppm</p> <p>NMT 890 ppm</p> <p>NMT 1000 ppm</p> <p>NMT 1000 ppm</p> <p>NMT 1000 ppm</p>