

**PRODUCT: AZITHROMYCIN DIHYDRATE**

<b>ITEMS</b>	<b>SPECIFICATIONS</b>
<b>APPEARANCE</b>	White or almost white crystalline powder
<b>SOLUBILITY</b>	Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride
<b>IDENTIFICATION</b> a) IR b) HPLC	Conforms to Azithromycin RS Conforms to Azithromycin RS
<b>SPECIFIC OPTICAL ROTATION</b>	-45° ~ -49°
<b>CRYSTALLINITY</b>	Meets the requirements
<b>PH</b>	9.0~11.0
<b>WATER</b>	4.0% ~ 5.0%
<b>RESIDUE ON IGNITION</b>	NMT 0.3%
<b>HEAVY METALS</b>	NMT 25ppm

<p><b>RELATED SUBSTANCES</b></p> <ul style="list-style-type: none"> <li>➤ <b>Azithromycin-N-oxide</b></li> <li>➤ <b>3'-(N-N-Didemethyl-3'-N-formylazithromycin</b></li> <li>➤ <b>Aminoazithromycin</b></li> <li>➤ <b>Azithromycin related compound F</b></li> <li>➤ <b>Desosaminylazithromycin</b></li> <li>➤ <b>N-Dimethyl azithromycin</b></li> <li>➤ <b>Azithromycin C (3'-o-demethylazithromycin)</b></li> <li>➤ <b>3'-De(dimethylamino)-3'-oxoazithromycin</b></li> <li>➤ <b>Azaerythromycin A</b></li> <li>➤ <b>Azithromycin impurity P</b></li> <li>➤ <b>2-Desethyl-2-propylazithromycin</b></li> <li>➤ <b>3'-N-Demethyl-3'-N-[(4-methylphenyl)sulfonyl]azithromycin</b></li> <li>➤ <b>Azithromycin B</b></li> <li>➤ <b>Any individual, unidentified impurity</b></li> <li>➤ <b>Total impurities</b></li> </ul>	<p>NMT 0.5%</p> <p>NMT 0.5%</p> <p>NMT 0.5%</p> <p>NMT 0.5%</p> <p>NMT 0.3%</p> <p>NMT 0.7%</p> <p>NMT 0.5%</p> <p>NMT 0.5%</p> <p>NMT 0.5%</p> <p>NMT 0.2%</p> <p>NMT 0.5%</p> <p>NMT 0.5%</p> <p>NMT 1.0%</p> <p>NMT 0.2%</p> <p>NMT 3.0%</p>
<p><b>ASSAY (On the anhydrous basis)</b></p>	<p>945 u g/mg ~ 1030 u g/mg</p>
<p><b>RESIDUAL SOLVENTS</b></p> <ul style="list-style-type: none"> <li>➤ <b>Acetone</b></li> <li>➤ <b>Methanol</b></li> <li>➤ <b>Dichloromethane</b></li> </ul>	<p>NMT 3200 ppm</p> <p>NMT 3000 ppm</p> <p>NMT 600 ppm</p>
<p><b>BULK DENSITY</b></p>	<p>0.35~0.65 g/ml</p>
<p><b>TAPPED DENSITY</b></p>	<p>0.65~0.85 g/ml</p>
<p><b>PARTICLE SIZE DISTRIBUTION</b></p>	<p>Not less than 80% passes through 40mesh</p>