

**PRODUCTO: METRONIDAZOL**

ITEMS	SPECIFICATIONS
<b>IDENTIFICATION</b>	Positive reaction
<b>MELTING POINT</b>	159°C~163°C
<b>LOSS ON DRYING</b>	0.5% Max
<b>SULPHATED ASH</b>	0.1% Max
<b>HEAVY METALS</b>	20 ppm max
<b>APPEARANCE OF SOLUTION</b>	Pass
<b>RELATED SUBSTANCES</b> ➤ <b>Single impurity</b> ➤ <b>Total impurities</b>	Pass 0.1% max 0.2% max
<b>RESIDUAL SOLVENTS=&gt; Ethanediol</b>	10 ppm max
<b>NON BASIC SUBSTANCES</b>	Pass
<b>SPECIFIC ABSORBANCE</b>	365~389
<b>ASSAY</b>	99.0% ~101.0% C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>3</sub>

**METRONIDAZOL BENZOATO**

ITEMS	SPECIFICATIONS
<b>DESCRIPTION</b>	White or slightly yellowish crystalline powder
<b>SOLUBILITY</b>	Practically insoluble in water, freely soluble in methylene chloride, soluble in acetone, slightly soluble in alcohol

<p><b>IDENTIFICATION</b></p> <p>a) <b>Melting range</b></p> <p>b) <b>UV</b></p> <p>c) <b>IR</b></p> <p>d) <b>Primary aromatic amines test</b></p>	<p>99°C ~ 102°C</p> <p>The light absorption in the range 220 nm and 350 nm the solution shows 2 absorption maxima, at 232 nm and 275 nm. The specific absorbance at maximum at 232 nm is 525 to 575</p> <p>Infrared absorption spectrum of sample in KBr dispersion is concordant with infrared absorption spectrum of Metronidazole Benzoate working standard or Metronidazole Benzoate reference spectrum</p> <p>An intense orange or red colour precipitates produce</p>
<p><b>APPEARANCE OF SOLUTION</b></p>	<p>Not more opalescent than reference suspension II and not more intensely coloured than reference solution GY<sub>3</sub></p>
<p><b>ACIDITY</b></p>	<p>NMT 0.25 ml of 0.02 M NaOH is required to change the colour of the indicator</p>
<p><b>RELATED SUBSTANCES</b></p> <ul style="list-style-type: none"> <li>➤ <b>Impurity A</b></li> <li>➤ <b>Impurity B</b></li> <li>➤ <b>Impurity C</b></li> <li>➤ <b>Other impurity</b></li> <li>➤ <b>Total impurities</b></li> </ul>	<p>NMT 0.1%</p> <p>NMT 0.1%</p> <p>NMT 0.1%</p> <p>NMT 0.1%</p> <p>NMT 0.2%</p>
<p><b>HEAVY METALS</b></p>	<p>NMT 20 ppm</p>
<p><b>SULPHATED ASH</b></p>	<p>NMT 0.1%</p>
<p><b>LOSS ON DRYING</b></p>	<p>NMT 0.5%</p>
<p><b>ASSAY</b></p>	<p>98.50% ~ 101.0%</p>
<p><b>PARTICLE SIZE</b></p>	<p>40 Mesh not less than 98%</p>