

**PRODUCT: CYCLOSPORINE HCL**

ITEMS	SPECIFICATIONS
<b>DESCRIPTION</b>	White to almost white powder
<b>SOLUBILITY</b>	Soluble in acetone, in methanol, in ethanol 96% v/v, in ether, in chloroform, and in methylene chloride. Slightly soluble in saturated hydrocarbons. Practically insoluble in water
<b>IDENTIFICATION (HPLC)</b>	The chromatogram of the assay preparation obtained as directed under the test for assay exhibits a major peak for cyclosporine, the retention time of which corresponds to that exhibited in the chromatogram of the reference standard/working standard preparation, as obtained under the test for assay
<b>LOSS ON DRYING</b>	NMT 2.0% w/w, determined on 100 mg in a capillary stoppered bottle in vacuum at a pressure not exceeding 5mm of mercury at 60°C for 3 hrs.
<b>HEAVY METALS</b>	NMT 0.002%
<b>RELATED COMPOUNDS (HPLC)</b> a) Any individual impurity b) Total impurities	NMT 0.7% NMT 1.5%
<b>ASSAY BY HPLC (on dried basis)</b>	98.5% ~ 101.5% (C <sub>62</sub> H <sub>111</sub> N <sub>11</sub> O <sub>12</sub> )
<b>RESIDUAL SOLVENTS</b> ➤ Acetone ➤ Ethyl acetate	NMT 4500 ppm NMT 2000 ppm
<b>PARTICLE SIZE DISTRIBUTION</b> a) Less than 100 µm b) Less than 50 µm	Not less than 90% Not less than 70%