

**PRODUCT: PREDNISOLONE**

| ITEMS  | SPECIFICATIONS   |
|--|--|
| <b>CHARACTERISTICS</b>   | White or almost white crystalline powder   |
| <b>IDENTIFICATION</b>  | A;B  |
| <b>SPECIFIC OPTICAL ROTATION</b>   | +113° ~ +119°  |
| <b>RELATED SUBSTANCES</b> <ul style="list-style-type: none"> <li>➤ Impurity A (hydrocortisone)</li> <li>➤ Impurity B (prednisone)</li> <li>➤ Impurity C (prednisolone acetate)</li> <li>➤ Impurity F (11-epi-prednisolone)</li> <li>➤ Impurity J (11-deoxyprednisolone)</li> <li>➤ Unspecified impurity</li> <li>➤ Total impurities</li> </ul> | <ul style="list-style-type: none"> <li>≤1.0%</li> <li>≤0.3%</li> <li>≤0.3%</li> <li>≤0.5%</li> <li>≤0.3%</li> <li>≤0.10%</li> <li>≤1.5%</li> </ul> |
| <b>LOSS ON DRYING</b>  | ≤1.0%  |
| <b>ASSAY</b>   | 96.5% ~ 102.0%   |
| <b>RESIDUAL SOLVENTS</b> <ul style="list-style-type: none"> <li>a) Methanol</li> <li>b) Acetone</li> </ul>   | <ul style="list-style-type: none"> <li>≤700 ppm</li> <li>≤200 ppm</li> </ul>   |
| <b>PARTICLE DISTRIBUTION</b><br>(In house criteria) <ul style="list-style-type: none"> <li>➤ 80%</li> <li>➤ 98%</li> </ul>   | <ul style="list-style-type: none"> <li>≤15 μm</li> <li>≤30 μm</li> </ul>   |