

PRODUCTO: PREDNISOLONA

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