

PRODUCT: PREDNISONE ANHYDROUS MICRONIZED

ITEMS	SPECIFICATIONS
DESCRIPTION	White to practically white crystalline powder
IDENTIFICATION a) IR b) Colorimetric reaction	According to reference standard Positive
SPECIFIC OPTICAL ROTATION	+167° ~ 175° (c=0.5, dioxane, 25°C)
WATER	≤1.0%
RESIDUE ON IGNITION	Negligible
HPLC CHROMATOGRAPHIC PURITY ➤ Prednisone-21-acetate ➤ 11-Deoxyprednisone ➤ Cortisone ➤ Each unknown ➤ Total	≤0.50% ≤0.50% ≤0.50% ≤0.10% ≤2.0%
ASSAY HPLC (anhydrous basis)	97.0% ~ 102.0%
RESIDUAL SOLVENTS a) Methanol b) Methyl ethyl ketone	<500 ppm <1000 ppm
PARTICLE SIZE ➤ 100% ➤ 90%	≤15 μm ≤5 μm
TAPPED DENSITY	0.20 g/ml ~ 0.50 g/ml