

PRODUCTO: DIPROPIONATO DE BETAMETASONA MICRONIZADO ESTÉRIL

ITEMS	SPECIFICATIONS
DESCRIPTION	A white to cream white, odorless powder
SOLUBILITY	Practically insoluble in water, freely soluble in acetone and in chloroform, sparingly soluble in ethanol (96%)
IDENTIFICATION => Test A & B	Test A & B
SPECIFIC OPTICAL ROTATION (on dried basis)	+63° ~ +70°
LOSS ON DRYING	NMT 1.0%
RESIDUE ON IGNITION	NMT 0.2%
CHROMATOGRAPHIC PURITY a) Any individual impurity b) Total impurities	NMT 1.0 % NMT 2.0 %
ASSAY (On dried basis)	97.0% ~ 103.0%
RESIDUAL SOLVENTS ➤ Methylene chloride ➤ Acetone ➤ Ethyl Acetate ➤ Methanol ➤ Pyridine	NMT 600 ppm NMT 5000 ppm NMT 5000 ppm NMT 3000 ppm NMT 200 ppm
PARTICLE SIZE < 30 Microns	99.0%
STERILITY	As per USP