

PRODUCTO: SIMVASTATINA

ITEMS	SPECIFICATIONS
CHARACTERISTICS	White to off-white powder
SOLUBILITY	Practically insoluble in water, freely soluble in chloroform, in methanol and in alcohol; sparingly soluble in propylene glycol; very slightly soluble in hexane
IDENTIFICATION	a) IR : Conforming b) The retention time of the major peak: conforming
SPECIFIC ROTATION	+285° ~ +298°
LOSS ON DRYING	≤0.5%
CHROMATOGRAPHIC PURITY	
➤ Simvastatin hydroxyacid	≤0.4%
➤ Epilovastatin and lovastatin	≤1.0%
➤ Methylene Simvastatin	≤0.4%
➤ Acetyl simvastatin	≤0.4%
➤ Anhydro simvastatin	≤0.4%
➤ Simvastatin dimer	≤0.4%
➤ Any other individual impurity	≤0.1%
➤ Total impurities other than lovastatin and epilovastatin	≤1.0%