

PRODUCT: PRAVASTATIN SODIUM

ITEMS	SPECIFICATIONS
APPEARANCE	White to yellowish white powder or crystalline powder
IDENTIFICATION a) IR Spectroscopy b) Identification of Na	IR Spectrum conforms with the reference spectrum Positive for sodium
SPECIFIC ROTATION	+150° ~ +160°
PH	7.2 ~ 9.0
WATER	NMT 4.0%
HEAVY METALS	NMT 0.002%
ASSAY	97.5% ~ 102.0% (on the anhydrous basis)
RELATED SUBSTANCES ➤ Total impurities ➤ 3''-Hydroxypravastatin ➤ 6´-Epiprasvastatin ➤ 3α-Hydroxyisocompactin ➤ Pentanoyl impurity ➤ Pravastatin Lactone ➤ Compactin ➤ Any other individual impurity	NMT 0.6% NMT 0.2% NMT 0.3% NMT 0.2% NMT 0.2% NMT 0.2% NMT 0.2% NMT 0.1%
RESIDUAL SOLVENTS a) Acetone b) Butyl acetate	NMT 5000 ppm NMT 5000 ppm