PRODUCTO: ROSUVASTATINA CÁLCICA

ITEMS	SPECIFICATIONS
DESCRIPTION	A off-white to light yellow coloured crystalline powder
SOLUBILITY	Soluble in N,N-Dimethylformamide, Dichloromethane and insoluble in water
IDENTIFICATION **a) IR** **b) Test for calcium** **c) HPLC**	The sample spectrum should be in concordant with that of Rosuvastatin working standard Shall respond to test for calcium The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay
WATER CONTENT BY KF	NMT 6.0% w/w
CALCIUM CONTENT	3.5% w/w ~ 4.5% w/w
SPECIFIC OPICAL ROTATION	+14.0º ~ +19.0º
HEAVY METALS	NMT 20 ppm
PURITY (By HPLC) **a) Single major unknown impurity** **b) Total impurities**	 NMT 0.5% NMT 1.0%
ASSAY BY HPLC (on anhydrous basis)	98.0% w/w ~ 102.0% w/w