

PRODUCTO: ATORVASTATINA CÁLCICA TRIHIDRATO

ITEMS	SPECIFICATIONS
DESCRIPTION	A white or almost white crystalline powder
SOLUBILITY	Slightly soluble in ethanol, practically insoluble in methylene chloride
IDENTIFICATION a) I.R. b) Test for calcium	IR absorption spectrum of the sample should be concordant with that of the standard Should comply the test
WATER CONTENT	3.5% ~5.5% w/w
HEAVY METALS	≤ 20ppm
RELATED SUBSTANCES (HPLC) ➤ Epoxide-atorvastatin ➤ Atorvastatin lactone ➤ Desfluoro- atorvastatin calcium ➤ Diamine- atorvastatin calcium ➤ Difloruro- atorvastatin calcium ➤ Isomer- atorvastatin calcium ➤ Other individual unknown impurity ➤ Total impurities	≤ 0.1 % ≤ 0.1 % ≤ 0.3 % ≤ 0.3 % ≤ 0.3 % ≤ 0.3 % ≤ 0.1 % ≤ 1.0 %
ASSAY (on anhydrous basis)	98.0 % w/w ~102.0% w/w