



CERTIFICATE OF ANALYSIS

PRODUCT NAME : VINBLASTINE SULPHATE

TEST	OBSERVATION	LIMITS
DESCRIPTION	A WHITE CRYSTALLINE POWDER ODOURLESS, HYGROSCOPIC	A WHITE OR SLIGHTLY YELLOW AMORPHOUS OR CRYSTALLINE POWDER, ODOURLESS HYGROSCOPIC
SOLUBILITY	CONFORMS	FREELY SOLUBLE IN WATER
IDENTIFICATION	CONFORMS CONFORMS	TO CONFORMS (I.R.) TO CONFORMS (HPLC)
PH	4.30	BETWEEN 3.5 TO 5.0
LOSS ON DRYING	8.00% W/W	NOT MORE THAN 15.0% W/W
RELATED COMPOUNDS (BY HPLC) INDIVIDUAL IMPURITY TOTAL IMPURITY	0.70% 1.50%	NOT MORE THAN 1.0% NOT MORE THAN 3.0%
ASSAY (HPLC)	98.5%	NOT LESS THAN 96.0% & NOT MORE THAN 102% W/W (ON ANHYDROUS BASIS)
BACTERIAL ENDOTOXINS	CONFORMS	NOT MORE THAN 10.0 USP ENDOTOXINS UNITS PER MG OF VINCALEUKOBLASTINE SULPHATE