

PRODUCT: NIFEDIPINE

ITEMS	SPECIFICATIONS
DESCRIPTION	Yellow crystalline powder, readily affected exposure to light
SOLUBILITY	Freely soluble in acetone and in chloroform, sparingly soluble in ethanol, practically insoluble in water
IDENTIFICATION	To comply tests A,B, & C as per USP
MELTING RANGE	171°C ~ 175°C
HEAVY METALS	NMT 10 ppm
RELATED SUBSTANCES (By HPLC) ➤ Each ➤ Total	0.2% 0.4%
RESIDUE ON IGNITION	NMT 0.10%
LOSS ON DRYING	NMT 0.50%
ASSAY (on dried basis)	98.0% ~ 102.0%
PERCHLORIC ACID TITRATION	NMT 0.12ml of 0.1 perchloric acid/gm
CHLORIDE AND SULPHATE a) Chloride b) Sulphate	NMT 0.02% NMT 0.05%
ORGANIC VOLATILE IMPURITIES	Meets the requirements of USP
EXTRANEIOUS MATTER	10% w/v solution in acetone should contain no extraneous matter