

PRODUCT: METFORMIN HYDROCHLORIDE

ITEMS	SPECIFICATIONS
DESCRIPTION	White or almost white crystalline powder
SOLUBILITY	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride
IDENTIFICATION B) IR spectrum E) Chloride test	It should be concordant with working standard White precipitate is formed
APPEARANCE OF SOLUTION	Clear and colourless solution
RELATED SUBSTANCES (BY HPLC) ➤ Impurity A ➤ Individual unknown impurity	NMT 0.02% NMT 0.1%
HEAVY METALS	NMT 10 ppm
LOSS ON DRYING	NMT 0.5%
SULPHATED ASH	NMT 0.1%, determined on 1.0g
ASSAY (BY TITRATION) (on dried substance)	98.5% ~ 101.0%
PARTICLE SIZE	100% pass through 40 mesh