



PRODUCT: CLARITHROMYCIN GRANULE 40%

ITEMS	SPECIFICATIONS
CHARACTERISTICS	White to off white tasteless free flowing granules
IDENTIFICATION	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
PARTICLE SIZE	Not less than 90% granules in 30-80 mesh
PH	3.5~6.5
LOSS ON DRYING	5.0% max
RESIDUE ON IGNITION	0.5% max
HEAVY METALS	20 ppm max
DISSOLUTION TEST (in 0.1N HCL)	15% max
DISSOLUTION TEST (in phosphate butter PH 6.8)	Not less than 80%
ASSAY	37.80%~46.20%