

PRODUCTO: OMEPRAZOLE PELLETS 8.5%

ITEMS	SPECIFICATIONS
DESCRIPTION	A white to off-white coloured spherical pellets
IDENTIFICATION BY HPLC	The retention time of the main peak in the HPLC chromatogram under assay should be same as that of standard
MOISTURE CONTENT BY KF	NMT 3.0% w/w
BULK DENSITY	0.70 ~ 0.90 gm/ml
GASTRIC RESISTANCE	NLT 85.0% w/w material should remain undissolved in 0.1N HCl after 2 hrs.
DISSOLUTION IN PHOSPHATE BUFFER (ph 6.8)	NLT 75.0% w/w of the Omeprazole should be dissolved in phosphate buffer (ph 6.8) within 45 minutes
PELLET SIZE	NLT 95% pellets should pass through 12 mesh and NMT 5% pellets should pass through 16 mesh
ASSAY	8.10% w/w ~ 8.90% w/w