



**PRODUCT: ESOMEPRAZOLE ENTERIC COATED PELLETS (8.5% W/W)**

<b>ITEMS</b>	<b>SPECIFICATIONS</b>
<b>DESCRIPTION</b>	White to off- white spherical pellets
<b>IDENTIFICATION</b>	Complies with the test for HPLC
<b>MOISTURE CONTENT (By K.F. Method)</b>	NMT 3.0% w/w
<b>GASTRIC RESISTANCE (By HPLC)</b>	Not less than 85% drug shall be retained in 0.1 N HCL at 100 RPM after 2 hours
<b>DISSOLUTION (By HPLC)</b>	Not less than 75% of the drug should be dissolved in 45 minutes in 900ml of 6.8 pH buffer.
<b>ASSAY (By HPLC) Esomeprazole 8.5% w/w (as Esomeprazole Magnesium Trihydrate USP)</b>	8.075% w/w ~ 8.925% w/w (95% ~105% of the label claim)