

Certificate of Analysis

Product name	Esomeprazole magnesium trihydrate		
Batch No.	RY20151202	CAS No.	217087-09-7
Mfg. Date	18 th ,Dec,2015	Exp. Date	17 th ,Dec,2017
Standard	EP8.2	Packing	10KG/drum

Tests	Specifications	Result
Appearance	White or slight coloured powder,slightly hygroscopic	Slightly coloured powder
Solubility	Slightly soluble in water,soluble in methanol,practically insoluble in heptane	Complies
Identity	The spectra obtained should be in accordance with that of Esomeprazole magnesium trihydrate CRS(IR)	Complies
	It should give the reaction of magnesium	Complies
Absorbance	≤0.20(440nm)	0.09
Magnesium content	Calculation on anhydrous substance basis,3.30%~3.55%	3.31%
Water determination	6.2%~8.0%	7.20%
R-omeprazole	≤0.2%	Not be detected
Related substances	Omeprazole sulfone ≤0.10%	0.01%
	Any other individual related substance≤0.10%	0.03%
	Total impurities≤0.3%	0.09%
Residual solvents	Methylene chloride≤600ppm	Not be detected
	Methylbenzene ≤890ppm	Not be detected
	Methanol≤3000ppm	38ppm
	Ethyl acetate≤5000ppm	Not be detected
Heavy metal	≤ 20 ppm	Complies

Assay (by anhydrous basis)	98.0%~102.0%	99.6%
Conclusion : Conforms to EP8.2.		

Tested by: Alice

Checked by: Penny

Approved by: Michelle