

Certificate of Analysis

Product Name		esomeprazole magnesium trihydrate	Packing	10kg per drum
Batch No.		D10043-20220101	Quantity	210kg
Mfg. Date		Jan.11, 2022	Report Date	Feb.08, 2022
Retest Date		Jan.10, 2024	According to	EP10.0 and in house
ITEM		SPECIFICATION		TEST RESULT
Appearance		White or slightly coloured powder, slightly hygroscopic.		Slightly coloured powder, slightly hygroscopic
Solubility		Slightly soluble in water, soluble in methanol, practically insoluble in heptane.		Complies
Identification	1	The spectra obtained should be in accordance with that of esomeprazole magnesium trihydrate CRS (IR).		Complies
	2	It should give the reaction of magnesium.		Complies
Absorbance		Not more than 0.20 (440 nm)		0.053
Magnesium content (on the anhydrous basis)		3.30%~3.55%		3.35%
Water determination		6.2%~8.0%		7.05%
R-omeprazole		Not more than 0.2%		Not be detected
Related substances	Omeprazole sulfone	Not more than 0.15%		0.021%
	Any other individual impurity	Not more than 0.10%		0.043%
	Total impurities	Not more than 0.3%		0.08%
Residual solvents	Methylene chloride	Not more than 600 ppm		Not be detected
	Methylbenzene	Not more than 890 ppm		52.18ppm
	Methanol	Not more than 3000 ppm		26.82ppm
	Ethyl acetate	Not more than 5000 ppm		Not be detected
Heavy metals		Not more than 20 ppm		Complies
Assay (on the anhydrous basis)		98.0 % - 102.0 %		99.8%
Conclusion		Comply with EP10.0 and in house		

QC Director:

李培培

Rechecker:

米云芬

Checker:

王 振

2022.02.08

2022.02.08

2022.02.08

2022.02.08

