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CERTIFICATE OF ANALYSIS

Product name	ESOMEPRAZOLE MAGNESIUM (TRIHYDRATE) 埃索美拉唑镁三水合物		
Batch No.	20130220	**CAS NO**	217087-09-7
Report Date	2013-02-26	**Expiry date**	2015-02

TEST	STANDARDS	RESULTS
Description 性状	White to slightly colored powder 白色至微有颜色粉末	White powder 白色粉末
Solubility 溶解性	Soluble in methanol, slightly soluble in water, practically insoluble in heptane 在甲醇中溶解，微溶于水，几乎不溶于庚烷	Conforms 符合规定
Identification 鉴别 a) IR b) AAS	Sample spectrum should match with working standard. 供试品红外光谱应与对照品一致 Sample spectrum as described in the test of magnesium. （λmax=285. 2nm）AAS 显镁盐鉴别反应 λmax=285. 2nm	Conforms 符合规定 Conforms 符合规定
Colour of Solution at 440 nm (2.0 % w/v solution in methanol) 440nm 波长处吸收度	≤0.2	0.056
Specific Rotation at 20 ℃ (1.0% w/v solution in methanol On Anhydrous basis) 旋光度（1%甲醇，以干品计）	137.0 ° ~ - 142.0 °	-140.25°
Water 水份	6.0 %~ 8.0%	7.48%
Chromatographic Purity（HPLC） HPLC 纯度	a)N-Oxide Analogue N-氧化物类似物≤ 0.1% b)Sulfone Analogue 砜类似物 ≤ 0.2% c)Benzimidazole Analogue 苯并咪唑类似物≤ 0.1% d)Dis-methoxy Analogue 甲氧基类似物≤ 0.1% e)Sulphide Analogue 硫化物类似物≤ 0.1% f)Any other Individual Impurity 其他任一单杂≤ 0.1% g)Total Impurities 总杂质≤ 0.5%	0.03% 0.05% Conforms Conforms Conforms 0.02% 0.15%
Enantiomeric Purity 对映体纯度	a) Purity 纯度≥ 99.8% b)R-Omeprazole R-奥美拉唑≤ 0.2%	99.90% 0.10%
Magnesium Content 镁	3.30%~3.55%(On Anhydrous Basis)以干品计	3.39%
Assay by HPLC HPLC 含量	98.0 %~102.0%(On Anhydrous Basis)	99.40%
Residual Solvents by GC-HS 溶剂残留	a)Methylene Chloride 二氯甲烷≤ 600ppm b)Methanol 甲醇≤ 3000ppm c)Acetone 丙酮≤ 5000ppm d)Ethyl Acetate 乙酸乙酯≤ 5000ppm e)Toluene 甲苯≤ 890ppm	Not detected 未检出 187ppm 73ppm 395ppm Not detected 未检出
Conclusion 结论：conforms to USP34 符合美国药典 USP34 标准		

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