杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Esomeprazole magnesium Trihydrate

Batch No.: DR20150221	**Piece:**1.0kg
Manufacture Date: 2015.02.21	**Expiry Date:** 2017.02

TESTS:

Items	Specification	Results
Description	White to slightly colored powder	An Off White powder
Solubility	Soluble in methanol, slightly soluble in water, practically soluble in heptane	Conforms
Identification by a) IR b) AAS	Sample spectrum /Absorption should match with standard	Conforms Conforms
Colour of Solution at 440 nm (2.0 % w/v solution in methanol)	≤0.2	0.06
Specific Rotation at 20 ℃(1.0% w/v solution in methanol)(On Anhydrous basis）	–137.0 ° ～–142.0°	-139.80 °
Water (%w/w)	6.0% to 8.0 %	7.30%
Chromatographic Purity by HPLC (%)	a) N-Oxide Analogue. ≤0.1% b) Sulfone Analogue ≤0.2% c) Benzimidazole Analogue ≤0.1% d) Dis-methoxy Analogue ≤ 0.1% e) Sulphide Analogue ≤0.1% f) Any other Individual Impurity≤0.1% g) Total Impurities≤ 0.5%	0.02% 0.06% BDL BDL BDL 0.05% 0.16%
Enantiomeric Purity (%)	a) Purity NLT 99.5% b) R-Omeprazole ≤0.2%	99.75% 0.15%
Magnesium Content (% w/w) (On Anhydrous Basis）	3.30% to 3.55%	3.42%
Assay by HPLC (% w/w) (On Anhydrous Basis)	98.0 % to 102.0%	99.42%

Add:1018 Guangyin Building No.42 E. Fengqi Road,Hangzhou,310012 China
Tel:+86-571- 85335020 **Fax: +86-571- 86948329**
E-mail: agnes@dawnraypharma.com **Website: http://www.dawnraypharma.com/**

Residual Solvents by GC-HS (ppm)	a) Methylene Chloride ≤600ppm	BDL
	b) Methanol ≤ 3000ppm	BDL--159
	c) Acetone ≤ 5000ppm	BDL
	d) Ethyl Acetate ≤ 5000ppm	BDL
	e) Toluene≤ 900ppm	BDL
Conclusion: The results conform to the USP34 standard.		

Analyst: Joe Yu **Checker: Agnes Zhong** **QA.Manager: Sun Wenhu**

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