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

CERTIFICATE OF ANALYSIS

Esomeprazole sodium

Batch No.: DR20140411	**Piece:**1.0kg
Manufacture Date: 2014.04.11	**Expiry Date:** 2016.04.10

TESTS:

Items	Specification	Results
Description	White to an off-white powder ;hygroscopic in nature	An Off -White powder
Solubility	Freely soluble in water ,soluble in propylene glycol;sparingly soluble in alcohol and methanol	Conforms
Identification by	a) UV：0.002% solution in 0.1m NaOH exhibits absorption maximum at 305nm and 276nm and the ratio is 1.6 to1.8 b) IR：the IR spectrum should be concordant with the IR spectrum of the working standard c) Test for sodium： the residue on ignition gives reaction of sodium	a）1.73 b）Conforms c）Conforms
Appearance of solution (2.0 % w/v aqueous solution)	Should be clear	A clear solution
PH (2.0 % w/v aqueous solution)	10.3 to 11.3	10.5
Water by KF (%w/w)	≤6.0%	1.8%
Specific Rotation at 25 ℃ (1.0% w/v solution in methanol)	-38 ° ~–48.0°	-47.5°
Heavy metals as pb	≤20ppm	Conforms
Purity and related substances by HPLC (%)	a) Purity ≥ 99.5% b) Total impurities ≤0.5% c) individual impurity ≤0.2%	99.93% 0.07% 0.03%
Assay by HPLC (% w/w) (On Anhydrous Basis)	98.0 % to 102.0%	99.59%
Residual Solvents by GC-HS (ppm)	a) Methylene Chloride ≤ 600ppm b) Methanol≤ 3000ppm c) Ethyl Acetate ≤ 5000ppm d) Toluene ≤ 890ppm	BDL BDL 640ppm BDL
Conclusion: The results conform to the USP35 standard.		

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