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CERTIFICATE OF ANALYSIS

Product name 产品名称	ESOMEPRAZOLE SODIUM 埃索美拉唑钠		
Batch No. 批号	20120312	CAS No.	161796-78-7
Report Date 报告日期	2012-03-26	Expiry date 有效期	2014-03

TEST	STANDARDS	RESULTS
Description 性状	White to an off-white powder,hygroscopic in nature 白色或类白色粉末，具吸湿性	Off-white powder 类白色粉末
Solubility 溶解性	Freely Soluble in water,soluble in propylene glycol,sparingly soluble in alcohol and methanol 易溶于水，在丙二醇中溶解，在甲醇和乙醇中略溶.	Conforms 符合规定
Identification 鉴别	a)UV：0.002% solution in 0.1M NaOH exhibits absorption maximum at 305nm and 276 nm and the ratio is 1.6 to 1.8 0.002% 的NaoH溶液(C_{NaOH}=0.1mol/L)在305nm和276nm处有最大吸收,二者比率为1.6~1.8	1.73
	b)IR：The IR spectrum should be concordant with the IR spectrum of the working standard 供试品的红外图谱应与对照品的红外图谱一致	Conforms 符合规定
	c)Test for sodium：The residue on ignition gives reaction of sodium 应显钠盐的化学反应	Conforms 符合规定
Appearance of solution (2.0 % w/v aqueous solution) 溶液澄清度（2%水溶液）	Should be clear 应澄清无色	A clear solution 澄清无色
PH(2% w/v aqueous solution)	10.3 ~11.3	10.45
Water by KF (%w/w) 水份	≤6.0%	0.32%
Specific optical rotation （25° C，1.0% w/v solution in methanol) 比旋度	-38° ~ -48°	-47.52°
Heavy Metal 重金属	≤20ppm	<20ppm
Purity and related substances （ HPLC ）纯度	a)Purity 纯度≥99.5%	99.96%
	b)total impurities 总杂≤0.5%	0.04%
	c)individual impurity 单杂≤0.1%	0.02%
Assay （HPLC） 含量	98.0%~102.0%(On Anhydrous Basis 以干品计)	99.60 %
Residual Solvents 溶剂残留	a)Methylene chloride 二氯甲烷≤600ppm	Not detected 未检出
	b)Methanol 甲醇≤3000ppm	Not detected 未检出
	c)Ethyl Acetate 乙酸乙酯≤5000ppm	301ppm
	d)Toluene 甲苯≤890ppm	Not detected 未检出
Conclusion 结论：Conforms to enterprise standard 本品符合企业内控标准.		

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