


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

CERTIFICATE OF ANALYSIS

Erythromycin Base

Batch No.: DR20130410	Quantity: 463kg
Manufacture Date: 2013.04.10	Expiry Date: 2017.03

TESTS:

Items	Specification	Results
Appearance	White crystalline powder	Conforms
Identification	IR absorption spectrum comparison with USP RS	Conforms
Specific rotation	-71.0°~-78.0°	-74.0°
Erythromycin A enol other	≤3.0%	0.2%
Erythromycin B	≤12.0%	2.1%
Erythromycin C	≤5.0%	3.2%
Any individual related substance	≤3.0%	2.4%
Limit of thiocyanate	≤0.3%	0.1%
Water	≤10.0%	4.4%
Residue on ignition	≤0.2%	0.1%
Assay	85.0%~100.5%	97.9%
Erythromycin A	85.0%~100.5%	91.4%
Residual solvents	Ethanol:≤0.5% Acetone:≤0.5% Propanol:≤0.5% N-butyl acetate:≤0.5%	0.0021% 0.0050%
		
Conclusion: The results conform to USP35.		

Analyst: _____

Checker: _____

QA.Manager: _____

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