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

CERTIFICATE OF ANALYSIS

Cefuroxime Sodium

Batch No.: DR20110601	Piece: 15 cartons+1 carton	
Package Size: 10kg/tin/carton	Specification: USP and Enterprise standard	
Date Of Testing: 2011.06.13	Date Of Report: 2011.06.17	
Manufacture Date: 2011.06.01	Expiry Date: 2014.05	

TESTS:

Items	Specification	Results
Characteristics	White or yellowish powder	White powder
Identification	1) The retention time of the principal peak of the substance to be examined in the chromatogram corresponds to that exhibited in the chromatogram of standard preparation obtained as directed in the assay.	Conforms
	2) It responds to the tests for Sodium.	Conforms
PH	6.0~8.5	6.4
Water	≤3.5%	1.9%
Sterilty	Meets the specifications	Conforms
Bacterical endotoxins	<0.10 USP EU/mg Cefuroxime	Conforms
Visible Particles	Meets the specifications	Conforms
Particulate matter	≥10μm; ≤2000pc/g	1326pc/g
	≥25μm; ≤200pc/g	88pc/g
Residual solvents	Acetone: ≤5000ppm	1558ppm
	Methanol: ≤3000ppm	344ppm
Assay	855~1000ug/mg C16H16N4O8S (Calculated on the anhydrous basis)	953ug/mg

Conclusion: The results conform with USP and Enterprise standard.

Checked by: Approved by: LITY STAMP

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