

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

CERTIFICATE OF ANALYSIS

Cefotaxime Sodium Sterile

<b>Batch No.:</b> DR20120116	<b>Piece:</b> 220kg
<b>Package Size:</b> 10kg/tin/carton	<b>Specification:</b> USP34
<b>Manufacture Date:</b> 2012.01.16	<b>Expiry Date:</b> 2014.12

**TESTS:**

Items	Specification	Results
Characteristics	Off-white to pale yellow crystalline powder	A white crystalline powder
Solubility	Freely soluble in water,practically insoluble in organic solvents	Conforms
Clarity and color of solution	1) The solution is clear 2) Absorbance $\leq 0.20$	Conforms 0.048
Identification	1) Infrared absorption 2) The retention time of major peak of cefotaxime in the chromatogram of the assay preparation corresponds to that exhibited in the chromatogram of the standard preparation. 3) It responds to the tests for sodium.	Conforms
Specific rotation	$+58.0^{\circ} \sim +64.0^{\circ}$	$+62.0^{\circ}$
PH	4.5~6.5	5.1
Loss on drying	$\leq 3.0\%$	1.1%
Chromatographic purity	1) Any impurity $\leq 1.0\%$ 2) Total impurity $\leq 3.0\%$	0.47% 1.4%
Sterility	Meets the specifications	Conforms
Bacterial endotoxins	$< 0.20$ USP EU/mg cefotaxime	Conforms
Particulate matter	$\geq 10\mu\text{m}; \leq 2000\text{pc/g}$ $\geq 25\mu\text{m}; \leq 200\text{pc/g}$	510pc/g 10pc/g
Acetone	$\leq 5000\text{ppm}$	405ppm
Methanol	$\leq 3000\text{ppm}$	216ppm
Ethyl acetate	$\leq 5000\text{ppm}$	3891ppm
Isopropyl alcohol	$\leq 5000\text{ppm}$	178ppm

Add:1018 Guangyin Building No.42 E. Fengqi Road, Hangzhou, 310012 China

Tel: +86-571- 85335020

E-mail: agnes@dawnraypharma.com

Fax: +86-571- 85335020

Website: <http://www.dawnraypharma.com>

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Assay	916~964ug/mg C16H17N5O7S2 (Calculated on the dried basis)	962ug/mg
Conclusion: The results conform with USP34.		



Checked by: \_\_\_\_\_

Approved by: \_\_\_\_\_

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