

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

CERTIFICATE OF ANALYSIS

Cefazedone sodium

Batch No.: DR20140424	Quantity: 17.23kg
Manufacture Date: 2014.04.24	Expiry Date: 2016.04.23

TESTS:

Items	Specification	Results
Appearance	White to yellowish white powder	Almost white powder
Identification	1) The infrared spectra of cefazedone sodium and cefazedone sodium RS exhibit similar intensities of absorption at the same wavenumbers. 2) The principle spots from the test solution and the standard solution show the same RF value. 3) It responds to the test(1) for sodium.	Conforms
Specific optical rotation	-3° ~+4°	-3°
PH	4.5~6.5	5.3
Specific absorbance	490~570	506
Heavy metal	≤20ppm	Conforms
Water	≤2.0%	2.0%
Residue on ignition	12.0%~12.8%	12.7%
Residue solvents	Dichloromethane: ≤0.06% N,N-Dimethylformamide: ≤0.088%	0.005% 0.041%
Bacterial endotoxins	≤0.016EU/mg	Conforms
Sterility	Meets the requirements when tested as directed for membrane filtration under test	Conforms
Assay(on dried basis)	≥86.5% of Cefazedone C ₁₈ H ₁₅ Cl ₂ N ₅ O ₅ S ₃	94.8%

Conclusion: The results conform to KPC standard.



Analyst: Joe Yu **Checker:** Agnes Zhong **QA.Manager:** Sun Wenhu

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

Tel: +86-571- 85335020

Fax: +86-571- 85335020

E-mail: agnes@dawnraypharma.com

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