

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

**CERTIFICATE OF ANALYSIS**

**Cefminox Sodium**

<b>Batch No.:</b> DR20130207	<b>Quantity:</b> 550.0kg
<b>Manufacture Date:</b> 2013.02.07	<b>Expiry Date:</b> 2015.02.06

**TESTS:**

Items	Specification	Results
Description	White or light yellow crystalline powder	Conforms
Identification	A: The retention time of the major peak of the sample corresponds to that of the standards in assay. B: UV maximum absorption at 272nm C: It responds to the tests for sodium. D: Hydroxamic acid iron reaction	Conforms
Absorbance	195~220 (272nm)	207
Specific rotation	+76° ~ +89°	+82°
Clarity and color	Clear or clarity of solution: ≤ 1# Color: ≤ Y5#	Clear =Y1#
Water	18.0%~20.0%	18.6%
Heavy metals	≤ 10ppm	Conforms
Particular matter	Particle equal to or greater than 10um ≤ 6000 Particle equal to or greater than 25um ≤ 600	88 6
Residual solvents	Dichloramine: ≤0.06% Acetone: ≤0.5% Isopropanol: ≤0.5% Ethyl acetate: ≤0.5% Anisole: ≤0.5%	N.D. 0.03% 0.02% 0.006% N.D.
Related substances	Any impurity: ≤0.7% Total impurities: ≤2.0%	0.4% 0.8%
Bacterial endotoxins	< 0.05EU/mg	Conforms
Sterility	Conforms with the requirements	Conforms
Assay	91.0%~98.5%(on the anhydrous and solvent free of cefminox of C16H21N7O7S3)	93.90%
Conclusion: The results conform to the standard.		

**Analyst:** \_\_\_\_\_

**Checker:** \_\_\_\_\_

**QA.Manager:** \_\_\_\_\_

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