

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

CERTIFICATE OF ANALYSIS

Ampicillin trihydrate

<b>Batch No.:</b> DR20120720	<b>Piece:</b> 1075kg
<b>Package Size:</b> 25kg/drum	<b>Specification:</b> CP2010
<b>Manufacture Date:</b> 2012.07.20	<b>Expiry Date:</b> 2014.06

**TESTS:**

Items	Specification	Results
Characteristics	A white crystalline powder	A white crystalline powder
Specific optical rotation	+280° ~+305°	+300°
Identification	The retention time of principal peak of the substance being examined is identical with that of ampicillin CRS.The infrared absorption spectrum is concordant with that of ampicillin CRS.	Conforms
PH	3.5~5.5	4.4
Appearance of solution	In hydrochloric acid: ≤ suspension II In ammonia: ≤ suspension II	0.5 0.5
Related substances	≤ 1.0%	0.3%
Total impurities	≤ 3.0%	0.8%
N,N-Dimethylaniline	≤ 20ppm	Not detected
Residual solvents	Methylene chloride: ≤ 0.11% Isopropyl alcohol: ≤ 0.5%	0.035% 0.002%
Water	12.0%~15.0%	13.2%
Residue on ignition	≤ 0.5%	0.1%
Heavy metals	≤ 20ppm	Conforms
Assay (on the anhydrous basis)	≥96.0%	98.9%

Conclusion: The results conform with CP2010.

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

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

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



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