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

CERTIFICATE OF ANALYSIS

Moxolactam sodium

Batch No.: DR20141103	**Quantity:** 200g
Manufacture Date: 2014.11.03	**Expiry Date:** 2016.11.05

TESTS:

Items	Specification	Results
Appearance, physical character	White to light yellowish powder or block	Conforms
Identification	（1）The retention time of principle peak of Test Solution is in accordance with that of the principle peak of Reference Solution.	Conforms
	（2）Its IR spectrum is in accordance with that of its reference standard.	Conforms
	（3）It responds to the Sodium Test.	Conforms
Clarity of Solution	Clear and colourless; ≤1# turbidity standard solution.	＜ref susp 1
Color of Solution	≤6# of yellow or green yellow	＜Y6
PH	5.0~7.0	6.5
Water	≤5.0%	3.6%
Related Substances	Moxolactam R, S isomer two peak separation degree should not be less than 3 degrees of separation, two peak and the adjacent impurity peak should meet the requirements. Such as impurity peaks in the chromatogram of the test solution, a single impurity peak area shall not be greater than the control solution two peak area and 2 times (2%), the area of each impurity peak and shall not be greater than the control solution two peak area and 5 times (5%)	Conforms
Isomer	R: S peak area ratio 0.8-1.4	1.1

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/**

Residual Solvents	Ethyl acetate, Acetone, MEK, Dichloromethane and methanol by internal standard method by peak area ratio shall comply	Conforms
Bacterial endotoxin	≤0.050 EU/mg	Conforms
Assay	It contains not less than 830μg/mg of C20H20N6Na2O9S, calculated on the anhydrous basis.	856μg
Conclusion: The results conform to the JP16 standard.		

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

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