

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

CERTIFICATE OF ANALYSIS

Ropivacaine Hydrochloride Monohydrate

Batch No.: DR20110219	Quantity: 10kg
Manufacture Date: 2011.02.19	Expiry Date: 2013.02.18

TESTS:

Items	Specification	Results
Appearance	White powder	White powder
Identification (A) (B)	A) Infrared Absorption B) A solution(1 in 100) responds to the test for Chloride.	Conforms
Color	The absorbance at 405nm and at 436nm,the absorbance at 405nm is not more than 0.030,and the absorbance at 436nm is not more than 0.025.	Conforms
Clarity	Meets the requirements	Conforms
PH	4.5~6.0	4.85
Related substance	Total impurity: ≤0.5% Single impurity: ≤0.1% Bupivacaine: ≤0.2%	0.3% 0.02% N.D.
Enantiomeric purity	R enantiomer ≤0.5%	0.01%
Water	5.0%~6.0%	5.39%
Heavy metals	≤0.001%	Conforms
Limit of 2,6-Dimethylaniline	≤10ppm	1.0ppm
Specification	-210.0° ~-255.0°	-248.0°
Assay	98.5%~101.0%	99.45%

Conclusion: The results conform with USP30.



Analyst: _____

Checker: _____

QA.Manager: _____

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