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CERTIFICATE OF ANALYSIS

Product	ROPIVACAINE HCL		
Batch No.	20111207	CAS	132112-35-7
Test Date	2011.12.20	Expiry date	2013.12

Inspection Items	Accepted Standard	Results
Appearance	White,crystalline powder.Soluble in water	Complies
Identification	A: By IR, To match with working standard	Complies
	B: Test for chlorides. Reponds to the test for Chlorides.	Complies
Bacterial endotoxins	Meets the requirements	Complies
Colour	Meets the requirements	Complies
Clarity	Meets the requirements	Complies
Specific rotation	-210°~ -255°	-249°
pH	4.5 ~ 6.0	5.76
Water	5.0%~6.0%	5.19%
Heavy metal	≤ 10ppm	Complies
Limit of ropivacaine related compound A	≤10µg/g	Complies
Related compounds	Bupivacaine≤0.2%	Complies
	other individual impurity≤0.1%	Complies
	Total impurities ≤0.5%	0.04%
Enantiomeric purity	≤0.5%	0.20%
Residual Solvents	Meets the requirements	Complies
Assay	98.5~101.0%	99.96%
Conclusion: Conforms to USP34		

Analyst :lixin

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