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CERTIFICATE OF ANALYSIS

Product name	Bupivacaine hydrochloride		
Batch No.	20121102	Expiry date	2014.11
Report Date	2012.11.13	Quantity	200kg

Inspection Items	Accepted Standard	Results
Appearance	White ,odorless,crystalline powder	Complies
Solubility	Freely soluble in water and in alcohol;slightly soluble in chloroform and in acetone	Complies
Identification	A: By IR, To match with working standard	Complies
	B: By UV, To match with working standard	Complies
	C: Chloride test, To Matching with the standard	Complies
Related Substances	Should be to match with the standard	Complies
PH	4.5 ~ 6.0	5.38
Water	4.0%~6.0%	5.21%
Residue on ignition	≤ 0.1%	0.04%
Heavy metals	≤ 0.001%	<0.001%
Limit of residual solvents	Alcohol ≤2.0%	Not detect
	Isopropylic alcohol ≤2.0%	Not detect
Chromatographic purity	Should be to match with the standard	Complies
Assay	98.5~101.5%	99.72%
Conclusion : Complies to the USP34 standard		

Analyst :lichao

Checker: shilijuan

Supervisor :maohongjun