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CERTIFICATE OF ANALYSIS

Product Name	Ropivacaine Hydrochloride	CAS No.	854056-07-8
Batch No.	P011060617A	Mfg. Date	Oct. 21, 2017
Quantity	200kg	Retest Date	Oct. 20, 2019
Packing	25kg/Drum	Report Date	Oct. 29, 2017
Specification	USP38		

ITEM	SPECIFICATION	RESULT
Appearance	White crystalline powder	White crystalline powder
Solubility	Soluble in water	Complies
Identification	A. IR: The IR spectrum of sample is identical with that of reference standard	Complies
	B. Chloride	Complies
Colour	The absorbance at 405nm is not more than 0.030	0.006
	The absorbance at 436nm is not more than 0.025	0.005
Clarity	Meets the requirements	Complies
pH	4.5 ~ 6.0	5.23
Water	5.0%~6.0%	5.68%
Related Substances		
Bupivacaine	≤0.2%	Undetected
Any Other Individual Impurity	≤0.1%	0.03%
Total Impurities	≤0.5%	0.06%
Enantiomeric purity	≤ 0.5%	Undetected
Assay	98.5~101.0%	99.69%
Residual Solvents	Meets the requirements	Complies
Conclusion	The product conforms to USP38.	
Remarks	N/A	

Analyst:

QC Manager:

QA: