

CERTIFICATE OF ANALYSIS

Product Name	Rocuronium Bromide		
Batch No.	090704	Date of Manufacturing	Jul. 17,2009
Quantity	1Kg	Date of Retest	Jul. 16,2011
CAS No.	119302-91-9	Reference Standard	EP6.0
ITEMS	SPECIFICATION		RESULTS
Appearance	Almost white or pale yellow powder		Complied
Solubility	Freely soluble in water and anhydrous ethanol		Complied
Identification			
a) IR Spectrum (KBr)	Must comply with EP6.0		Complied
b) Bromide Test	Must comply with EP6.0		Complied
Test			
Appearance of Solution	Must comply with EP6,0		Complied
Specific Optical Rotation	Between +28.5°~+32.0°		+29.8°
pH	Between 8.9~9.5		9.12
Heavy Metals	Not more than 10ppm		Complied
Water Content	Not more than 4.0%		2.7%
Sulphated Ash	Not more than 0.1%		0.05%
Chlorides	Not more than 0.1%		0.03%
Total Impurities	Not more than 1.5%		0.27%
Unknown Impurities (each)	Not more than 0.05%		0.04%
Impurity A	Not more than 0.2%		0.08%
Impurity B	Not more than 0.3%		Nil
Impurity C	Not more than 0.3%		0.04%
Impurity D	Not more than 0.1%		Nil
Impurity E	Not more than 0.1%		Nil
Impurity F	Not more than 0.1%		0.09%
Impurity G	Not more than 0.1%		Nil
Impurity H	Not more than 0.1%		Nil
Residual Solvents			
Acetone	Not more than 0.5%		0.02%
Dichloromethane	Not more than 0.06%		0.03%
Ether	Not more than 0.5%		0.07%
Methanol	Not more than 0.3%		Nil
Assay of Rocuronium Bromide On Anhydrous Basis	Not less than 99.0% and not more than 101.0%		100.6%
Conclusion: The sample complies with specification of EP6.0 .			

Analyst: Xu Ke ,Yang Yue, Li Yujin, Kang Li