

CERTIFICATE OF ANALYSIS

Product Name	Rocuronium Bromide	Batch NO.	RY181213
Production date	2018.12.13	Expired Date	2020.12.12
CAS NO.	119302-91-9	Standard	EP standard
<b>Tests</b>	<b>Limits</b>		<b>Test results</b>
Appearance	Almost white or pale yellow, slightly hygroscopic powder		Off-white powder
Solubility	Soluble in water and ethalol, slightly soluble in glacial acetic acid, almost insoluble in ether		Conforms
Identification	IR:Spectrum should be consistent with the reference spectrum of rocuronium bromide		Conforms
	Bromide test should be positive		positive
Appearance of solution	Should meet requiriement		Conforms
Specific optic rotation	+28.5° and +32.0°		+31.8°
PH	7.0~9.5		9.2
Related substances	Total impurity≤1.5%		0.34%
	The single impurity≤0.1%		0.01%
	Impurity A≤0.2%		0.06%
	Impurity B≤0.3%		0.04%
	Impurity C≤0.3%		0.15%
	Impurity D≤0.1%		0.01%
	Impurity E≤0.1%		N.D.
	Impurity F≤0.1%		0.05%
	Impurity G≤0.1%		0.005%
Residual solvent	Impurity H≤0.1%		0.002%
	Methanol ≤0.3%		0.13%
	Ether≤0.5%		0.004%
	Acetone≤0.5%		0.003%

	Acetonitrile $\leq$ 0.041%	N.D.
	Petroleum ether $\leq$ 0.029%	0.0004%
	Methylbenzene $\leq$ 0.089%	N.D.
	Dichloromethane $\leq$ 0.06%	0.04%
Heavy metals	$\leq$ 10ppm	Conforms
Water	$\leq$ 4.0%	2.2%
Bacterial endotoxins	$\leq$ 0.5EU/mg	Conforms
Microbial limit	Total aerobic bacteria $\leq$ 100cfu/g	Conforms
	Yeast and mold number $\leq$ 10cfu/g	Conforms
	Escherichia coli absent per 1g	Conforms
Residue on ignition	$\leq$ 0.1%	0.04%
Assay	98.0%~102.0%(anhydrous substance)	99.9%
Conclusion: This batch meets EP7.0 standard.		



Tested by: Esther

Checked by: Alice

Approved by: Mich