

## CERTIFICATE OF ANALYSIS

Product: Rocuronium Bromide intermediate  
Chemical name: (2b,3a,5a,16b,17b)-2-(4-morpholinyl)-16-(1-pyrrolidinyl)androstane-3,17-diol[CAS:119302-20-4]  
Batch No: 160801  
Manufacturing Date: Aug., 2016  
Expiry Date: Aug., 2020  
Quantity: 22.70 Kgs

Items	Specifications	Results
Appearance:	white to off-white crystalline powder	Complies
Identification:	IR spectrum	Complies
Loss on drying:	0.5%max.	0.1%
Water(KF):	0.5%max.	0.1%
Residue on ignition:	0.1%max.	0.02%
Specific rotation:	+82 <sup>0</sup> ~+89 <sup>0</sup>	+86.9 <sup>0</sup>
Residual solvents:		
Methanol:	300ppm max.	25ppm
Ethanol:	500ppm max.	Undetected
Acetone:	500ppm max.	4ppm
Dichloromethane:	600ppm max.	126ppm
Ethyl acetate:	500ppm max.	Undetected
Related substance(HPLC):		
Compound V :	0.2%max.	Undetected
Iso:	0.2%max.	Undetected
Dipyrrolidine D:	0.5%max.	0.45%
Impurity A at RRt~0.21:	1.7%max.	1.06 %
Impurity B at RRt~0.55:	0.6%max.	0.23%

Impurity C at RRt~1.26:	0.5%max.	Undetected
Any other unidentified:	0.2%max.	Undetected
Total impurities:	2.5%max.	1.45%
Assay(titration):	99.0%min.	99.6%
(calculated on dried basis)		
Morpholine:	0.2%max.	Undetected

**Conclusion:It Complies with the Enterprise's Standard .**

**QC manager:**

**Checked by:**

**Analyst:**