

No.: BPAP-602-A-00/3.0

CERTIFICATE OF ANALYSIS

Product Name	Dexmedetomidine Hydrochloride	CAS No.	145108-58-3
Batch No.	P010260219A	Mfg. Date	Feb. 12, 2019
Quantity	1000g	Retest Date	Feb. 11, 2019
Packing	Bag	Report Date	Feb. 17, 2019
Specification	Enterprise Standard		

ITEM	SPECIFICATION	RESULT
Appearance	White or off-white crystalline powder	White crystalline powder
Solubility	Freely soluble in water, ethanol and chloroform, practically insoluble in ether	Complies
Identification	A) UV B) IR C) Chloride identification	Complies
Melting Point	153-158°C	155-158°C
pH	3.5-5.5	4.20
Clarity and Color of Solution	Should be clear and colorless, if turbid and colored, not more nepheloid than turbidity-1, not more strong than yellow-1.	Less than turbidity-1, colorless
Specific Rotation	+51.0°~+54.0°	+53.10°
Loss on Drying	≤1.0%	0.07%
Residue on Ignition	≤0.1%	0.08%
Heavy Metals	≤20ppm	Complies
Assay	≥99.0%	99.78%
Related Substances		
-Levomedetomidine HCl	≤1.0%	0.033%
-Max unknown single impurity	≤0.1%	0.025%
-Total impurities	≤1.0%	0.10%
Residual Solvents		
-Methanol	≤3000ppm	Undetected
-Ethanol	≤5000ppm	Undetected
-Acetone	≤5000ppm	Undetected
-Ethyl acetate	≤5000ppm	Undetected
-Dichloromethane	≤600ppm	Undetected
Conclusion	Comply with the specification.	
Storage	Preserve in tight containers, protected from strong light and high heat.	

Analyst:

Reviewed by:

Approved by: