



四川青益纯医药科技有限公司  
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## CERTIFICATE OF ANALYSIS

<b>Product Name</b>	Dexmedetomidine Hydrochloride	<b>CAS No.</b>	145108-58-3
<b>Batch No.</b>	P010660217A	<b>Mfg. Date</b>	Jun. 06, 2017
<b>Quantity</b>	1000G	<b>Retest Date</b>	Jun. 05, 2019
<b>Packing</b>	Bag	<b>Report Date</b>	Jun. 15, 2017
<b>Specification</b>	Enterprise Standard		

ITEM	SPECIFICATION	RESULT
<b>Appearance</b>	White or off-white crystalline powder	White crystalline powder
<b>Solubility</b>	Freely soluble in water, ethanol and chloroform, practically insoluble in ether	Complies
<b>Identification</b>	A) UV B) IR C) Chloride identification	Complies
<b>Melting Point</b>	153-158°C	155-158°C
<b>pH</b>	3.5-5.5	4.15
<b>Clarity and Color of Solution</b>	Should be clear and colorless, if turbid and colored, not more nepheloid than turbidity-2, not more strong than yellow-1.	Less than turbidity-2, colorless
<b>Specific Rotation</b>	+51.0° ~ +54.0°	+53.42°
<b>Loss on Drying</b>	≤1.0%	0.11%
<b>Residue on Ignition</b>	≤0.1%	0.03%
<b>Heavy Metals</b>	≤10ppm	Complies
<b>Assay</b>	≥99.0%	99.77%
<b>Related Substances</b>		
Levomedetomidine HCl	≤0.15%	0.033%
Max unknown single impurity	≤0.1%	0.055%
Total impurities	≤0.5%	0.055%
<b>Residual Solvents</b>		
Methanol	≤3000ppm	Undetected
Ethanol	≤5000ppm	40ppm
Acetone	≤5000ppm	10ppm
Ethyl acetate	≤5000ppm	Undetected
Tetrahydrofuran	≤720ppm	Undetected
Dichloromethane	≤600ppm	Undetected
<b>Conclusion</b>	The product conforms to Enterprise Standard.	
<b>Remarks</b>	N/A	

Analyst:

QC Manager:

QA: