



## Certificate of Analysis

<b>Product name</b>	Dexmedetomidine	<b>Manufacture date</b>	Apr.20.2024
<b>Batch number</b>	SW240420	<b>Analysis date</b>	Apr.21.2024
<b>Batch quantity</b>	500kg	<b>Expiry date</b>	Apr.20.2026

<b>Analysis Item</b>	<b>Specification</b>	<b>Test results</b>
<b>Appearance</b>	White Powder	Conforms
<b>Odor</b>	Characteristic	Conforms
<b>Melting point</b>	154~158°C	156°C
<b>Specific optical rotation</b>	+51.5° ~+54.5°	+52.3°
<b>Identification</b>	In the chromatogram recorded under isomer test,the retention time of major peak in test solution should correspond to that of dexmedetomidine peak in system suitability solution	Conforms
	Maximum absorption at 263nm,minimum absorption at 243nm	Conforms
	The infrared absorption spectrum of this product should be consistent with that of the reference substance	Conforms
	It gives reaction of chloride.	Conforms
<b>The clarity and color of the solution</b>	The solution should be clear and colorless;if the color is developed,it should be not more intensely than the yellow standard colorimetric solution 1	Conforms
<b>PH</b>	3.8-4.8	4.2
<b>Relevant substances</b>	Impurity YM-Z1 should be NMT 0.1%	Not detected
	Impurity YM-1 should be NMT 0.1%	<0.04%
	Impurity YM-Z3 should be NMT 0.1%	Not detected
	Impurity YM-Z5 should be NMT 0.1%	<0.04%
	Individual unspecified impurity should be NMT 0.10%	<0.04%
	Total impurities should be NMT 0.3%	<0.04%
<b>Isomer</b>	NMT 0.15%	0.09%
<b>Residual solvents</b>	Chloroethane should be NMT 0.1%	0.0003%
	Ethyl ether should be NMT 0.5%	0.03%
	Dichloromethane should be NMT 0.06%	0.007%
<b>Dimethyl sulfoxide</b>	NMT 0.5%	0.02%

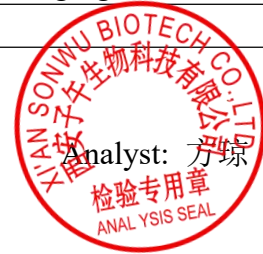


<b>Water</b>	NMT 1.5%	1.0%
<b>Residue on ignition</b>	NMT 0.1%	0.01%
<b>Heavy metal</b>	NMT 10ppm	Conforms
<b>Tartrate</b>	No turbidity	Conforms
<b>Chlorinity</b>	14.2%~15.7%	15.5%
<b>Bacterial endotoxins</b>	NMT 10EU/mg	Conforms
<b>Microbial Limit</b>	TAMC:NMT 103 cfu/g	<10cfu/g
	TYMC:NMT 102 cfu/g	<10cfu/g
<b>Conclusion</b>	Conforming to Enterprise Standard	

<b>Packing description:</b>	Sealed export grade drum & double of sealed plastic bag
<b>Storage:</b>	Store in cool & dry place. keep away from strong light and heat
<b>Shelf life:</b>	2 years when properly stored

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