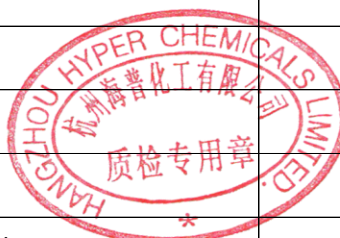


CERTIFICATE OF ANALYSIS

Product Name:	Sugammadex Sodium		
Batch No.	89221201	Batch size	28.90kg
Package size	10kg/drum	Packaging	Paperboard drum
Manufacturing Date	January 13, 2023	Test request Date	January 15, 2023
Sampling Date	January 15, 2023	Report Date	January 22, 2023
Retest period	36 months	Retest date	December, 2025
Analytical results			
Items	Specifications		Results
Appearance	White or off-white powder or granules and is highly hygroscopic.		White powder and is highly hygroscopic.
Identification	The retention time and UV absorption spectrum of the Sugammadex Sodium and the Monohydroxy Sugammadex Sodium in the chromatogram of the test solution should be correspond to the Sugammadex Sodium peak and the Monohydroxy Sugammadex Sodium in the chromatogram in the reference solution.		Conform
Solubility	Very soluble in water and practically insoluble in acetonitrile, methanol or absolute in ethanol.		Conform
Acidity or alkalinity	7.0~8.5		7.6
Appearance of solution	Solution should be clear; If color is developed, then the absorptivity should be less than 0.75 at 350nm.		The solution is clear and the absorptivity is 0.15 at 350nm.
Related substance 1	Impurity B: NMT 0.2%		0.03%
	Impurity C: NMT 0.2%		0.02%
	Impurity D: NMT 0.6%		0.10%
	Impurity E: NMT 0.6%		0.09%
	Impurity F: NMT 0.3%		0.01%
	Impurity G: NMT 1.3%		Not detected
	Impurity H: NMT 0.3%		0.09%
	Impurity L: NMT 0.3%		Not detected
	Impurity M: NMT 0.3%		0.10%
	Impurity N: NMT 1.0%		0.066%
	Impurity O or Impurity O': NMT 0.4%		0.05%



Items	Specifications	Results
Related substance 1	Impurity P or Impurity P': NMT 0.3%	Not detected
	Impurity Q: NMT 0.3%	0.04%
	Impurity R: NMT 0.3%	Not detected
	Impurity S or Impurity S': NMT 0.4%	Not detected
	Impurity T: NMT 0.3%	Not detected
	Acrylic acid: NMT 0.1%	Not detected
	Triphenylphosphine oxide: NMT 0.1%	Not detected
	Any other impurity: NMT 0.1%	0.078%
	Total impurities: NMT 5.0%	0.73%
Related substance 2	3-Mercaptopropionic acid: NMT 01%	Not detected
	3,3'-Thiodipropionic acid: NMT 0.1%	Not detected
	Impurity J (3,3'-Dithiodipropionic acid): NMT 0.1%	Not detected
Na	7.0%~9.0%	7.10%
Residual solvents	Methanol: NMT 0.02%	0.002%
	Ethanol: NMT 5.0%	1.60%
	N,N-dimethylformamide: NMT 0.088%	0.003%
Water	NMT 10.0%	3.74%
Iron salt	NMT 0.001%	Conform
Bromide	NMT 0.01%	Conform
Heavy metal	NMT 10ppm	Conform
Microbial limit	Number of bacteria: NMT 10 ³ cfu/g	Less than 20x10 ¹ cfu/g
	Number of fungi and yeast: NMT 10 ² cfu/g	Less than 10cfu/g
	Escherichia coli: Not detected/g	Not detected/g
Bacterial endotoxins	Less than 0.15EU/mg	Conform
Assay (on the anhydrous and ethanol free basis)	Sugammadex Sodium: 89.0%~102.0%	94.90%
	Monohydroxy Sugammadex Sodium should not more than 5.0%	1.40%
	Sum of Sugammadex Sodium and Monohydroxy Sugammadex Sodium: 94.0%~102.0%	96.30%
Conclusion	Meets the requirements of QS-1108	

Inspector: Carlifor Wu

Verifier: Jack He