Shandong Chenghui Shuangda Pharmaceutical Co., Ltd.
Certificate of Analysis

Request test No: 089221201 Report No: 2301065

Product name	Sugammadex Sodium			**Batch No**	089221201		
Package size	10kg/drum			**Packaging**	Paperboard drum		
Specification	QS-1108			**Manufacture**	Shandong Chenghui Shuangda Pharmaceutical Co., Ltd.		
Batch size	28.90kg	**Manufacture date**	23.01.13	**Test request date**	23.01.15		
Sampling date	23.01.15	**Report date**	23.01.22	**Retest period**	36 months	**Retest date**	2025.12.

Test items	**Acceptance criteria**		**Test results**	**Conclusion**
Appearance	White or off-white powder or granules and is highly hygroscopic.		White powder and is highly hygroscopic.	Conforms
Solubility	Very soluble in water and practically insoluble in acetonitrile, methanol or absolute in ethanol.		Very soluble in water and practically insoluble in acetonitrile, methanol or absolute in ethanol.	Conforms
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.		Conforms	Conforms
Acidity or alkalinity	7.0～8.5.		7.6	Conforms
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.	Conforms
Related substance 1	Impurity B	NMT 0.2%	0.03%	Conforms
	Impurity C	NMT 0.2%	0.02%	
	Impurity D	NMT 0.6%	0.1%	
	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%	0.1%	
	Impurity N	NMT 1.0%	0.066%	
	Impurity O or Impurity O′	NMT 0.4%	0.05%	
	Impurity P or Impurity P′	NMT 0.3%	Not detected	
	Impurity Q	NMT 0.3%	0.04%	

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Test items	Acceptance criteria		Test results	Conclusion
Related substance 1	Impurity R	NMT 0.3%	Not detected	Conforms
	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 0.10%	0.078%	
	Total impurities	NMT 5.0%	0.73%	
Related substance 2	3-Mercaptopropionic acid	NMT 0.1%	Not detected	Conforms
	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%		7.1%	Conforms
Residual solvents	Methanol	NMT 0.02%	0.002%	Conforms
	Ethanol	NMT 5.0%	1.6%	
	N, N-dimethylformamide	NMT 0.088%	0.0030%	
Water	NMT 10.0%		3.74%	Conforms
Iron salt	NMT 0.001%		Conforms	Conforms
Bromide	NMT 0.01%		Conforms	Conforms
Heavy metal	NMT 10ppm		Conforms	Conforms
Microbial limit	Number of bacteria	NMT 10^3cfu/g	Less than 20×10^1cfu/g	Conforms
	Number of fungi and yeast	NMT 10^2cfu/g	Less than 10cfu/g	
	Escherichia coli	Not detected/g	Not detected/g	
Bacterial endotoxins	Less than 0.15EU/mg		Conforms	Conforms
Assay (on the anhydrous and ethanol free basis)	Sugammadex Sodium:89.0%～102.0%		94.9%	Conforms
	Monohydroxy Sugammadex Sodium should not more than 5.0%		1.4%	
	Sum of Sugammadex Sodium and Monohydroxy Sugammadex Sodium : 94.0%～102.0%		96.3%	

Conclusion: Meets the requirements of QS-1108.

Quality responsible person: 超隋印海