ROYAL
ROYAL PHARM
瑾岚医药技术开发有限公司
JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED
Hangzhou ROYAL Import & Export Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product Name	Sugammadex Sodium	Batch NO.	RY2019.06.03
Production date	2019.06.03	Expired Date	2021.06.02
CAS NO.	343306-79-6	Standard	Enterprise standard

Tests	**Limits**	**Test results**
Appearance	White or off-white powder	White powder
Solubility	Soluble in water, unsoluble in the Methanol, ethanol or NN-dimethylformamide	Conforms
Specific rotation	+120° ~130°	+125.7°
Identification	Identification of sodium in aqueous solution of this product (2)	Conforms
	In the chromatogram recorded under the content determination, test the retention time of the two main peaks of the solution should be dissolved separately with the reference substance.Sodium glucosamine and mono-hydroxysulphate sodium in liquid Consistent retention time	Conforms
	The infrared absorption spectrum of this product should be compared with the reference map of the reference product.	Conforms
PH	7.0~9.0	8.2
Clarification of solution	The solution should be clear and colorless	Conforms
Related impurities	SGT-R4≤0.09%	0.03%
	SGT-R5≤0.09%	0.04%
	SGT-R6≤0.09%	N.D.
	SGT-R7≤0.09%	N.D.
	SGT-R12≤0.09%	0.06%
	SGT-R18≤0.09%	N.D.
	Any unknown impurity≤0.09%	0.02%

	Total impurity≤0.5%	0.13%
Residual solvent	Methanol≤0.3%	N.D.
	Ethanol≤0.5%	0.1553%
	NN-dimethylformamide≤0.088%	N.D.
	Dimethyl sulfoxide ≤0.5%	N.D.
Water	≤10.0%	3.0%
Na	7.6%~9.3%	8.12%
Assay	Calculated as anhydrous, solvent-free, containing Monohydroxyl- Sugammadex Sodium	0.04%
	Calculated as anhydrous and solvent-free substances, the content of Sugammadex Sodium should be 94.0%~102.0%.	97. 38%
	Calculated as anhydrous, solvent-free, containing monoterpene hydroxyl The sum of Sugammadex Sodium and Monohydroxyl- Sugammadex Sodium should be 97.0%~102.0%	97.4%
Conclusion: This batch meets enterprise standard.		

Tested by: Esther Checked by: Alice Approved by: Mich