HONOUR LAB LIMITED, Unit-III

Plot No. 4, Hetero Infrastructure Ltd-SEZ, N. Narasapuram (Village), Nakkapalli (Mandal),
Anakapalli (District)-531 081, Andhra Pradesh, India. Tel: 0091-891-2825999, Fax: 0091-891-2825933

CERTIFICATE OF ANALYSIS

Product	:	SUGAMMADEX SODIUM	STP No.	:	SD-003-12
Batch No.	:	SD23060001	Reference	:	In-house
Date of manufacture	:	June-2023	Batch quantity	:	10.66 kg
Re-test date	:	November-2027	Date of analysis	:	17/06/2023
Analytical Report No.	:	HR03FP23000919	Status	:	Re-certification

S. No.	Test	Specification		Result	Reference
	Assay by HPLC (% w/w, on anhydrous basis)	Not less than 92.0%w/w and not more than 102.0%w/w		97.7%w/w	USP < 621 > In-house
10.0	*Residual solvents by GC (ppm)	Methanol	: Not more than 3000 ppm	74 ppm	USP < 467 > In-house
		Ethanol	: Not more than 5000 ppm	1059 ppm	
		Methyl tertiary butyl ether	: Not more than 5000 ppm	Not detected	
		Toluene	: Not more than 890 ppm	Not detected	
		Dimethyl formamide	: Not more than 880 ppm	Not detected	
		Dimethyl sulfoxide	: Not more than 5000 ppm	Not detected	
11.0	Microbiology	Total aerobic microbial count (TAMC)	: Not more than 1000 cfu/g	Less than 10cfu/g	In-house
		Total combined yeast and mould count (TYMC)	: Not more than 100 cfu/g	Less than 10cfu/g	
12.0	Bacterial Endotoxin test (By Gel Clot method)	: Not more than 0.15 EU/mg		Less than 0.15 EU/mg	In-house

*No potential for any Class-1 solvents as specified by ICH or USP <467> to be present in the Sugammadex Sodium, as they are not used in the manufacturing process. The material, if tested for these solvents, will comply with the established standards.

The product conforms to above specifications.
#Customer requirement

Compiled by : Date : 21/12/2023

Checked by : Date : 21/12/23

Authorized signatory : KSP
Date : 21/12/23

HONOUR LAB LIMITED (UNIT III) * QUALITY ASSURANCE * QAD RELEASED 21/12/2023

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S. No.	Test	Specification	Result	Reference
1.0	Description	A white to an off-white powder.	An off-white powder	Visual inspection
2.0	Solubility	Freely soluble in water.	Complies	Visual inspection
3.0	Identification by			
3.1	IR(KBr)	The Infrared spectrum of the test sample should match with that of Sugammadex Sodium standard.	Matches	USP < 197K > In-house
3.2	HPLC	The retention time of the major peak in the chromatogram of the test solution should correspond to that of standard solution, as obtained in the assay by HPLC method.	Matches	USP < 621 > In-house
4.0	Water content by KF (%w/w)	Not more than 10.0%w/w	3.9%w/w	USP <921> In-house
5.0	Sodium content by Potentiometry (%w/w, on anhydrous basis)	Between 7.0%w/w to 9.0%w/w	7.9%w/w	USP < 281 > In-house
6.0	pH	Between 7.0 to 9.0	8.45	In-house
7.0	#Related compounds by HPLC(%)	Mono sulfoxide Sugammadex (Monosulfoxide impurity) :Not more than 0.50%	0.20%	USP < 621 > In-house
		Mono hydroxy Sugammadex (Monohydroxy impurity) :Not more than 4.0%	Below QL(QL=0.31%)	
		Sugammadex sulfide dimer (Sulfide dimer impurity) : Not more than 0.30%	0.17%	
		Sugammadex sulfide monomer(Sulfide monomer impurity): Not more than 0.20%	Below QL(QL=0.06%)	
		Monodisulfide Sugammadex (Monodisulfide impurity) :Not more than 0.30%	Below QL(QL=0.14%)	
		Mono thio Sugammadex (Monothio impurity) :Not more than 0.30%	Below QL(QL=0.11%)	
		Any unspecified impurity : Not more than 0.10%	0.08%	
		Total impurities (Excluding mono hydroxy impurity) : Not more than 2.0%	0.69%	
8.0	GCD content by HPLC (%)	Not more than 0.10%	Not detected	USP < 621 > In-house
9.0	Assay by HPLC (% w/w, on anhydrous basis) (Including mono hydroxy impurity)	Not less than 96.0%w/w and not more than 102.0%w/w	98.0%w/w	USP < 621 > In-house

Compiled by : Date : 21/12/2023

Checked by : Date :

HONOUR LAB LIMITED (UNIT-III) QAD RELEASED QUALITY ASSURANCE 21/12/2023

Authorized signatory : Date : 21/12/23