HONOUR LAB LIMITED, Unit-III
Plot No. 4, Hetero Infrastructure Ltd- SEZ,
N. Narasapuram (Village), Nakkapalli (Mandal),
Visakhapatnam (District) - 531081, Andhra Pradesh, INDIA.
Phone No. 0091-891-2825999, Fax: 0091-891-2825933

HONOUR

Certificate of Analysis

Product: SUGAMMADEX SODIUM					
Batch No.	SD19030001	**A.R.No(s)**	HR03FP20000967	**STP No.**	SD-003-11
Batch Quantity	12.17 Kg	**Reference**	In-house	**Date Of Manufacture**	Mar-2019
Date Of Release	28-10-2020	**Retest Date**	31-08-2021	**Exp. Date**	---

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	A White powder	A white to an off-white powder
2	**Solubility**	Complies	Freely soluble in water
3	**Identification by**		
3.1	**IR (KBr)**	Matches	The Infrared spectrum of the test sample should match with that of Sugammadex Sodium standard
3.2	**HPLC**	Matches	The retention time of the major peak in the chromatogram of the test solution should correspond to that of the standard solution, as obtained in the assay by HPLC method
4	**Water content by KF**	5.9%w/w	Not more than 10.0%w/w
5	**Sodium content by Potentiometry (On anhydrous basis)**	8.2%w/w	Between 7.0%w/w and 9.0%w/w
6	**pH**	7.78	Between 7.00 and 9.00
7	**Related compounds by HPLC**		
7.1	**Monosulfoxide Sugammadex (Monosulfoxide impurity)**	0.07 %	Not more than 0.50%
7.2	**Monohydroxy sugammadex (Monohydroxy impurity)**	0.84 %	Not more than 4.0%
7.3	**Sugammadex sulfide dimer (Sulfide dimer impurity)**	0.11 %	Not more than 0.30%
7.4	**Sugammadex Sulfide monomer (Sulfide monomer impurity)**	0.13 %	Not more than 0.20%
7.5	**Monodisulfide Sugammadex (Monodisulfide impurity)**	Below QL(QL=0.14%)	Not more than 0.30%
7.6	**Mono thio Sugammadex (Monothio impurity)**	Below QL(QL=0.11%)	Not more than 0.30%
7.7	**Any unspecified impurity**	0.07 %	Not more than 0.10%
7.8	**Total impurities (Excluding mono hydroxy impurity)**	0.72 %	Not more than 2.0%
8	**GCD Content by HPLC**		
8.1	**GCD Content**	Not Detected	Not more than 0.10%

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	**Reviewed By**	**Approved By**
Nandini.J	RameshKumar.G	Durga Raja.J
16-10-2021 11:59	16-10-2021 12:06	16-10-2021 16:20

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HONOUR

Certificate of Analysis

Product: SUGAMMADEX SODIUM					
Batch No.	SD19030001	**A.R.No(s)**	HR03FP20000967	**STP No.**	SD-003-11
Batch Quantity	12.17 Kg	**Reference**	In-house	**Date Of Manufacture**	Mar-2019
Date Of Release	28-10-2020	**Retest Date**	31-08-2021	**Exp. Date**	---

9	**Assay by HPLC (On anhydrous basis)(Including mono hydroxy impurity)**	100.1%w/w	Not less than 96.0%w/w and not more than 102.0%w/w
10	**Assay by HPLC (On anhydrous basis)**	99.1%w/w	Not less than 92.0%w/w and not more than 102.0%w/w
11	***Residual solvents by GC**		
11.1	**Methanol**	Below QL(QL=31.6ppm)	Not more than 3000ppm
11.2	**Ethanol**	77 ppm	Not more than 5000ppm
11.3	**Methyl tertiary butyl ether**	Not Detected	Not more than 5000ppm
11.4	**Toluene**	Below QL(QL=12.7ppm)	Not more than 890ppm
11.5	**Dimethyl formamide**	Not Detected	Not more than 880ppm
11.6	**Dimethyl sulfoxide**	Not Detected	Not more than 5000ppm
12	**Microbiology**		
12.1	**Total aerobic microbial count (TAMC)**	Less than 10 cfu/g	Not more than 1000 cfu/g
12.2	**Total combined yeast and mould count (TYMC)**	Less than 10 cfu/g	Not more than 100 cfu/g
13	**Bacterial Endotoxin test (By Gel Clot method)**	Less than 0.15	Not more than 0.15 EU/mg

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	**Reviewed By**	**Approved By**
Nandini.J	RameshKumar.G	Durga Raja.J
16-10-2021 11:59	16-10-2021 12:06	16-10-2021 16:20

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Certificate of Analysis

Product: SUGAMMADEX SODIUM					
Batch No.	SD19040002	**A.R.No(s)**	HR03FP20000968	**STP No.**	SD-003-11
Batch Quantity	12.39 Kg	**Reference**	In-house	**Date Of Manufacture**	Apr-2019
Date Of Release	28-10-2020	**Retest Date**	30-09-2021	**Exp. Date**	---

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	A White powder	A white to an off-white powder
2	**Solubility**	Complies	Freely soluble in water
3	**Identification by**		
3.1	**IR (KBr)**	Matches	The Infrared spectrum of the test sample should match with that of Sugammadex Sodium standard
3.2	**HPLC**	Matches	The retention time of the major peak in the chromatogram of the test solution should correspond to that of the standard solution, as obtained in the assay by HPLC method
4	**Water content by KF**	5.8%w/w	Not more than 10.0%w/w
5	**Sodium content by Potentiometry (On anhydrous basis)**	8.2%w/w	Between 7.0%w/w and 9.0%w/w
6	**pH**	7.94	Between 7.00 and 9.00
7	**Related compounds by HPLC**		
7.1	**Monosulfoxide Sugammadex (Monosulfoxide impurity)**	0.08 %	Not more than 0.50%
7.2	**Monohydroxy sugammadex (Monohydroxy impurity)**	0.85 %	Not more than 4.0%
7.3	**Sugammadex sulfide dimer (Sulfide dimer impurity)**	0.11 %	Not more than 0.30%
7.4	**Sugammadex Sulfide monomer (Sulfide monomer impurity)**	0.13 %	Not more than 0.20%
7.5	**Monodisulfide Sugammadex (Monodisulfide impurity)**	Below QL(QL=0.14%)	Not more than 0.30%
7.6	**Mono thio Sugammadex (Monothio impurity)**	Below QL(QL=0.11%)	Not more than 0.30%
7.7	**Any unspecified impurity**	0.07 %	Not more than 0.10%
7.8	**Total impurities (Excluding mono hydroxy impurity)**	0.73 %	Not more than 2.0%
8	**GCD Content by HPLC**		
8.1	**GCD Content**	Not Detected	Not more than 0.10%
9	**Assay by HPLC (On anhydrous basis)(Including**	100.3%w/w	Not less than 96.0%w/w and not more than 102.0%w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Reviewed By	Approved By
Nandini.J	RameshKumar.G	Durga Raja.J
16-10-2021 12:00	16-10-2021 12:06	16-10-2021 16:20

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HONOUR

Certificate of Analysis

Product: SUGAMMADEX SODIUM					
Batch No.	SD19040002	**A.R.No(s)**	HR03FP20000968	**STP No.**	SD-003-11
Batch Quantity	12.39 Kg	**Reference**	In-house	**Date Of Manufacture**	Apr-2019
Date Of Release	28-10-2020	**Retest Date**	30-09-2021	**Exp. Date**	---

	mono hydroxy impurity)		
10	**Assay by HPLC (On anhydrous basis)**	99.5%w/w	Not less than 92.0%w/w and not more than 102.0%w/w
11	***Residual solvents by GC**		
11.1	**Methanol**	Below QL(QL=31.6ppm)	Not more than 3000ppm
11.2	**Ethanol**	81 ppm	Not more than 5000ppm
11.3	**Methyl tertiary butyl ether**	Not Detected	Not more than 5000ppm
11.4	**Toluene**	Below QL(QL=12.7ppm)	Not more than 890ppm
11.5	**Dimethyl formamide**	Not Detected	Not more than 880ppm
11.6	**Dimethyl sulfoxide**	Not Detected	Not more than 5000ppm
12	**Microbiology**		
12.1	**Total aerobic microbial count (TAMC)**	Less than 10 cfu/g	Not more than 1000 cfu/g
12.2	**Total combined yeast and mould count (TYMC)**	Less than 10 cfu/g	Not more than 100 cfu/g
13	**Bacterial Endotoxin test (By Gel Clot method)**	Less than 0.15	Not more than 0.15 EU/mg

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	**Reviewed By**	**Approved By**
Nandini.J	RameshKumar.G	Durga Raja.J
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Certificate of Analysis

Product: SUGAMMADEX SODIUM					
Batch No.	SD19040003	**A.R.No(s)**	HR03FP20000969	**STP No.**	SD-003-11
Batch Quantity	12.26 Kg	**Reference**	In-house	**Date Of Manufacture**	Apr-2019
Date Of Release	28-10-2020	**Retest Date**	30-09-2021	**Exp. Date**	---

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	A White powder	A white to an off-white powder
2	**Solubility**	Complies	Freely soluble in water
3	**Identification by**		
3.1	**IR (KBr)**	Matches	The Infrared spectrum of the test sample should match with that of Sugammadex Sodium standard
3.2	**HPLC**	Matches	The retention time of the major peak in the chromatogram of the test solution should correspond to that of the standard solution, as obtained in the assay by HPLC method
4	**Water content by KF**	6.8%w/w	Not more than 10.0%w/w
5	**Sodium content by Potentiometry (On anhydrous basis)**	8.3%w/w	Between 7.0%w/w and 9.0%w/w
6	**pH**	8.01	Between 7.00 and 9.00
7	**Related compounds by HPLC**		
7.1	**Monosulfoxide Sugammadex (Monosulfoxide impurity)**	0.08 %	Not more than 0.50%
7.2	**Monohydroxy sugammadex (Monohydroxy impurity)**	0.85 %	Not more than 4.0%
7.3	**Sugammadex sulfide dimer (Sulfide dimer impurity)**	0.11 %	Not more than 0.30%
7.4	**Sugammadex Sulfide monomer (Sulfide monomer impurity)**	0.13 %	Not more than 0.20%
7.5	**Monodisulfide Sugammadex (Monodisulfide impurity)**	Below QL(QL=0.14%)	Not more than 0.30%
7.6	**Mono thio Sugammadex (Monothio impurity)**	Below QL(QL=0.11%)	Not more than 0.30%
7.7	**Any unspecified impurity**	0.07 %	Not more than 0.10%
7.8	**Total impurities (Excluding mono hydroxy impurity)**	0.73 %	Not more than 2.0%
8	**GCD Content by HPLC**		
8.1	**GCD Content**	Not Detected	Not more than 0.10%

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Reviewed By	Approved By
Nandini.J	RameshKumar.G	Durga Raja.J
16-10-2021 12:02	16-10-2021 12:06	16-10-2021 16:20

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HONOUR

Certificate of Analysis

Product: SUGAMMADEX SODIUM					
Batch No.	SD19040003	**A.R.No(s)**	HR03FP20000969	**STP No.**	SD-003-11
Batch Quantity	12.26 Kg	**Reference**	In-house	**Date Of Manufacture**	Apr-2019
Date Of Release	28-10-2020	**Retest Date**	30-09-2021	**Exp. Date**	---

9	**Assay by HPLC (On anhydrous basis)(Including mono hydroxy impurity)**	100.9%w/w	Not less than 96.0%w/w and not more than 102.0%w/w
10	**Assay by HPLC (On anhydrous basis)**	100.1%w/w	Not less than 92.0%w/w and not more than 102.0%w/w
11	***Residual solvents by GC**		
11.1	**Methanol**	Below QL(QL=31.6ppm)	Not more than 3000ppm
11.2	**Ethanol**	77 ppm	Not more than 5000ppm
11.3	**Methyl tertiary butyl ether**	Not Detected	Not more than 5000ppm
11.4	**Toluene**	Below QL(QL=12.7ppm)	Not more than 890ppm
11.5	**Dimethyl formamide**	Not Detected	Not more than 880ppm
11.6	**Dimethyl sulfoxide**	Not Detected	Not more than 5000ppm
12	**Microbiology**		
12.1	**Total aerobic microbial count (TAMC)**	Less than 10 cfu/g	Not more than 1000 cfu/g
12.2	**Total combined yeast and mould count (TYMC)**	Less than 10cfu/g	Not more than 100 cfu/g
13	**Bacterial Endotoxin test (By Gel Clot method)**	Less than 0.15	Not more than 0.15 EU/mg

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Reviewed By	Approved By
Nandini.J	RameshKumar.G	Durga Raja.J
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