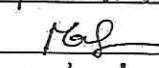
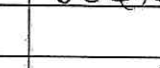
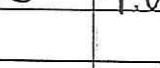


IN-HOUSE REFERENCE STANDARD CERTIFICATE OF ANALYSIS

Name of the standard	SUGAMMADEX SODIUM		
Batch No.	IRS/4041/22001	Reference	INH
Source Batch No.	4041/3/005/22	Quantity	50.0g
Date of Analysis	01/11/2022	Page No.	1 of 3
Valid up to	31/10/2023		

S. No.	TEST PARAMETER	SPECIFICATION	RESULT
01	Description	White to off white powder	White powder
02	*Solubility	Freely soluble in water, practically insoluble in anhydrous ethanol and in Propanol-2	Complies
03	Identification by		
	3.1 IR spectroscopy (KBr cm^{-1})	The IR spectrum of the sample should exhibit functional groups.	Complies
	3.2 * HPLC	The retention time of the major peak in the chromatogram of the sample preparation should correspond to that of the standard solution, as obtained in the assay by HPLC.	Complies
	3.3 *Sodium test	A Dense Precipitate should be formed	Complies
04	Water content by KF (%w/w)	Not more than 15.0	5.65
05	*Color of the solution	The absorption at 430 nm should be not more than 0.05	0.0103
06	*Clarity of the solution	solution should be clear	Complies
07	*P ^H (Concentration : 1.0 % in water)	7.0 to 9.5	7.98
08	Related substances by HPLC (% w/w)		
	a) Sulfoxide Diastereomer-I	Not more than 0.25	0.06
	b) Sulfoxide Diastereomer-II	Not more than 0.25	0.12
	c) Highest individual unspecified impurity	Not more than 0.08	0.04
	d) Total impurities	Not more than 1.0	0.31
09	*Mono Hydroxy content by HPLC(%w/w)	Not more than 3.0	1.1

	Prepared by	Checked by(Head -QC)	Approved by(Head -QA)
Name	P. Mahesh	K. S. S. Bakesh	T. V. Chalapati
Signature			
Date	01/11/2022	01/11/22	01/11/2022

Format No: QCD/112-F11-00

PLOT NO.: 40/A, J.N. PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM, A.P. INDIA

IN-HOUSE REFERENCE STANDARD CERTIFICATE OF ANALYSIS

Name of the standard	SUGAMMADEX SODIUM		
Batch No.	IRS/4041/22001	Reference	INH
Source Batch No.	4041/3/005/22	Quantity	50.0g
Date of Analysis	01/11/2022	Page No.	2 of 3
Valid up to	31/10/2023		

S. No.	TEST PARAMETER	SPECIFICATION	RESULT
10	*Acetic acid and Trifluoroacetic acid content by HPLC(%w/w)		
	Trifluoro acetic acid	Not more than 0.25	Not Detected
	Acetic acid	Not more than 0.50	0.06
11	*Gamma Cyclodextrin (KSM) content by HPLC(%w/w)	Not more than 0.08	Not Detected
12	*Assay by HPLC(Sugammadex sodium) (%w/w) (On anhydrous basis)	Not less than 95.0 and Not more than 102.0	98.3
13	*Assay by HPLC(Sugammadex sodium) (%w/w) (On anhydrous basis+Mono Hydroxy content)	Not less than 98.0 and Not more than 102.0	99.5
14	*Residual solvents by HS-GC (ppm)		
	Method-I		
	a) Methanol	Not more than 3000	BDL
	b) Tetrahydrofuran	Not more than 720	Not Detected
	c) Dichloromethane	Not more than 600	Not Detected
	d) Toluene	Not more than 890	BDL
	e) Methyl tertiary butyl ether	Not more than 5000	BDL
	f) Ethyl acetate	Not more than 5000	Not Detected
	Method-II		
	g) N,N-Dimethyl formamide	Not more than 880	BDL
	h) Dimethyl Sulfoxide	Not more than 5000	Not Detected
15	*Sodium content by ICP-MS (% on anhydrous basis)	Between 7.50 to 9.20	8.14
16	*Bacterial Endotoxin Test	Not More Than 0.15 EU / mg	Less than 0.15

	Prepared by	Checked by(Head -QC)	Approved by (Head-QA)
Name	P. Mahesh	K.S.S. Prakash	T. V. Subrahmanya Rao
Signature			
Date	01/11/2022	01/11/22	01/11/2022

Format No: QCD/112-F11-00

PLOT NO.: 40/A, J.N. PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM, A.P. INDIA

IN-HOUSE REFERENCE STANDARD CERTIFICATE OF ANALYSIS

Name of the standard	SUGAMMADEX SODIUM		
Batch No.	IRS/4041/22001	Reference	INH
Source Batch No.	4041/3/005/22	Quantity	50.0g
Date of Analysis	01/11/2022	Page No.	3 of 3
Valid up to	31/10/2023		

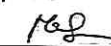
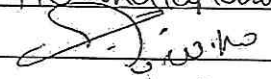
S. No.	TEST PARAMETER	SPECIFICATION	RESULT
17	*Microbial Limit Test		
	Total Aerobic Microbial Count	Not more than 1000 CFU/gm	100
	Total Combined Yeast and Molds Count	Not more than 100 CFU/gm	30
	Detection of Specified Pathogens		
	a) <i>Escherichia coli</i>	Shall be absent /gm	Absent
	b) <i>Staphylococcus aureus</i>	Shall be absent /gm	Absent
	c) <i>Pseudomonas aeruginosa</i>	Shall be absent/gm	Absent
	d) <i>Salmonella Species</i>	Shall be absent /gm	Absent
18	Mass Spectroscopy	Should conform to structure.	Complies
19	¹ H NMR	Spectra should show the protons at the predicted δ values with the predicted multiplicity	Conforms to their structure
20	¹³ C NMR	Spectra should show the carbons at the predicted δ values with the predicted multiplicity	Conforms to their structure
21	Elemental analysis	Should conforms to their CHNS values	Complies

Potency	92.9%
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*Indicates these results are taken from source batch.

Storage Conditions: Preserve in tightly closed containers at 25°C, Excursions permitted between 15 to 30°C

Remarks: The above material **complies/does not comply** as per the above specification.

	Prepared by	Checked by (Head -QC)	Approved by (Head-QA)
Name	P. Mahesh	K. S. S. Prakash	T. V. Chalapati Reddy
Signature			
Date	01/11/2022	01/11/22	01/11/2022

Format No: QCD/112-F11-00

PLOT NO.: 40/A, J.N. PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM, A.P. INDIA