AZICO BIOPHORE

Azico Biophore India Pvt. Ltd
425/3RT, Door No. 7-1-621/328
SR Nagar, Hyd-38, TS, INDIA
CIN NO.: U24233AP2008PTRC061809
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+91-40-2381 2709
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METAPHARMACEUTICAL

N DE LOTE: 0161123

20/11/2023

CERTIFICATE OF ANALYSIS

Product Name	**SUGAMMADEX SODIUM**		
Reference	**In-House**	Mfg. Date	**18/02/2022**
Batch No.	**4041/3/002/22**	Retest Date	**17/02/2025**
Date of Analysis	**02/03/2022**	Dispatch Qty.	**3.00 kg.**
Name of the Customer	**M/s. METAPHARMACEUTICALS IND SL.**		

S. No.	Test Parameter	Specification	Result
1.	Description	White to off white powder.	white powder
2.	Solubility	Freely soluble in water, practically insoluble in anhydrous ethanol and in Propanol-2	Complies
3.	Identification by		
	a) IR Spectroscopy (KBr cm^{-1})	The IR spectrum of the Absorption values of test sample should match with that of IR spectrum of standard.	Complies
	b) HPLC	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay in HPLC.	Complies
	c) Sodium test	A dense precipitate should be formed	Complies
4.	Water content by KF (%,w/w)	Not more than 15.0	8.29
5.	Color of the solution	The absorbance at 430 nm should be not more than 0.05	0.00
6.	Clarity of the solution	Solution should be clear.	Complies
7.	pH (Concentration: 1.0% in water)	7.0 to 9.5	8.47
8.	Related substance by HPLC (%w/w)		
	a) Sulfoxide Diastereomer-I	Not more than 0.25	0.13
	b) Sulfoxide Diastereomer-II	Not more than 0.25	0.20
	c) Highest Individual unspecified impurity	Not more than 0.08	0.05
	d) Total Impurities	Not more than 1.0	0.52
9.	Monohydroxy impurity content by HPLC (%w/w)	Not more than 3.0	2.3

Azico Biophore India Pvt. Ltd. Anakapalli

	Prepared By	Checked By	Approved By
Name	B. Eswara Rao	P. Appanna	Adapa. V. Uma Phani
Designation - Dept.	Chemist - QAD	Sr. Executive - QAD	Dy. Manager - QAD
Sign & Date	15/07/23	15/07/2023	15/07/23

PLOT NO.: 40/A, SY. NOS. 13,15,16,51,52,&182, J.N. PHARMA CITY, PARAWADA MANDAL, ANAKAPALLI DIST., A.P. INDIA

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S. No.	Test Parameter	Specification	Result
10.	Acetic acid and Trifluoroacetic acid content by HPLC(%, w/w)		
	Trifluoroacetic acid	Not more than 0.25	BDL
	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	98.2
13.	Assay by HPLC (Sugammadex Sodium) (%w/w) (on anhydrous basis + Monohydroxy impurity content)	Not less than 98.0 and Not more than 102.0	100.8
14.	Residual Solvents by HS-GC(ppm)		
	Method -I		
	a) Methanol	Not more than 3000	644
	b) Tetrahydrofuran	Not more than 720	Not detected
	c) Dichloromethane	Not more than 600	BDL
	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		
	a) N,N-Dimethyl formamide	Not more than 880	BQL
	b) Dimethyl Sulfoxide	Not more than 5000	Not detected
15.	Sodium content by ICP-MS(%, on anhydrous basis)	Between 7.50 to 9.20	9.17
16.	Bacterial Endotoxin Test (EU / mg)	Not more Than 0.15	Less than 0.15

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S. No.	Test Parameter	Specification	Result
17.	Microbial Limit Test		
	Total Aerobic Microbial Count (CFU/gm)	Not more than 1000	200
	Total Combined Yeast and Molds Count (CFU/gm)	Not more than 100	50
	Detection of Specified Pathogens		
	a) Escherichia coli	Shall be absent /gm	Absent
	b) Staphylococcus aureus	Shall be absent /gm	Absent
	c) Pseudomonas aeruginosa	Shall be absent/gm	Absent
	d) Salmonella Species	Shall be absent /gm	Absent

Chemical names of impurities:

Sulfoxide Diastereomer-I: Heptakis (6-S-(2-Carboxyethyl)-6-thio)-mono (6-S-(2-Carboxyethyl)- (R) - sulfinyl) cyclomaltooctaose.

Sulfoxide Diastereomer-II: Heptakis (6-S-(2-Carboxyethyl)-6-thio)-mono (6-S-(2-Carboxyethyl)-(S) sulfinyl) cyclomattooctaose.

Mono Hydroxy impurity: Heptakis (6-S-(2-Carboxyethyl)-6-thio)-γ-Cyclodextrin.

Packaging Conditions: Finished material shall be packed in transparent LDPE primary bag with nitrogen purging and tied with nylon strip. Then placed in black color LDPE secondary bag and tied with nylon strip. The same shall be placed in triple laminated aluminum bag and seal with heat and finally placed in HDPE container with clamp.

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

Remarks: The material Complies with the above specification.

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