

SUGAMMADEX SODIUM			
PRODUCT CODE: 151409		CAS Nº: 343306-79-6	ANALYSIS Nº: 027/25
MANUFACTURER BATCH:	4041/3/005/24	CERTIFICATE ID:	44.994
SUPPLIER BATCH:	----	MANUFACTURING DATE:	12/12/2024
METAPH BATCH:	0010225	EXPIRY DATE:	11/12/2029

ATTRIBUTES	SHOULD BE	IS
Description	White to off-white powder	White powder
Solubility	Freely soluble in water, practically insoluble in anhydrous ethanol and in 2-propanol	Complies (*)
Identification IR	Complies	Complies
Identification HPLC	Complies	Complies
Identification Sodium	Complies	Complies
Water	=< 15.0 %	3.1 %
Solution color		
Absorbance 430 nm	=< 0.05	0.00
Clarity of solution	Clear	Clear
pH	7.0 - 9.5	8.2
Related substances		
Sulfoxide Diastereomer-I	=< 0.25 %	0.12 %
Sulfoxide Diastereomer-II	=< 0.25 %	0.15 %
Any unspecified impurity	=< 0.08 %	< 0.05 %
Total impurities	=< 1.0 %	0.3 %
Monohydroxy impurity	=< 3.0 %	0.43 % (*)
Acid content		
Trifluoroacetic acid	=< 0.25 %	Not Detected
Acetic acid	=< 0.50 %	0.08 %
Gamma Cyclodextrin	=< 0.08 %	< 0.022%
Assay		
Sugammadex Sodium	95.0 - 102.0 %	98.3 %
Sugammadex Sodium + monohydroxy impurity	98.0 - 102.0 %	98.7 %
Residual solvents [In-house]		
Methanol	=< 3000 ppm	199 ppm
Tetrahydrofuran	=< 720 ppm	321 ppm
Methylene Chloride	=< 600 ppm	< 40 ppm (*)
Toluene	=< 890 ppm	96 ppm
tert-butyl methyl ether	=< 5000 ppm	< 13 ppm (*)
Ethyl acetate	=< 5000 ppm	< 50 ppm
Dimethylformamide	=< 880 ppm	25 ppm
Dimethyl Sulfoxide	=< 5000 ppm	121 ppm
Sodium	7.5 - 9.2 %	8.5 %
Bacterial endotoxines	=< 0.15 EU/mg	< 0.15 % (*)
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g
Staphylococcus aureus	Absence/1g	Absence/1g
Pseudomonas aeruginosa	Absence/1g	Absence/1g

Analysis date: 18/03/2025
 Signature: Cristina Borrell Olea (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000993
 AZICO BIOPHORE INDIA PVT.LTD
 Plot#92;1-98/2/92,Kavuri Hills -Phase II, Jubilee Hills
 531021 Andhra Pradesh





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Salmonella

Absence/1g

Absence/1g

COMPLIES WITH

Manufacturer Specifications

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Sugammadex Sodium is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the certificate of analysis of the manufacturer.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Preserve in tight, light-resistant containers.

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