METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

151409-TDS-ENG-2024

SUGAMMADEX SODIUM		
DESCRIPTION DCI: SUGAMMADEX SODIUM	DESCRIPTION DOE: SUGAMMADEX SODIO	
CAS Nº: 343306-79-6	EC Nº: 608-974-4	AEMPS CODE: 8282SO
MOL. WEIGHT: 2177,97	MOL. FORMULA: C72H104Na8O48S8	ARTICLE CODE: 151409

ATTRIBUTES	SHOULD BE
Description	White to off-white powder
Solubility	Freely soluble in water, practically insoluble in anhydrous ethanol and in 2-propranol
Identification IR	Complies
Identification HPLC	Complies
Identification Sodium	Complies
Water	=< 15.0 %
Colour of solution	
Absorvance 430 nm	=< 0.05
Clarity of solution	Clear
pH	7.0 - 9.5
Related substances	
Sulfoxide Diastereomer-I	=< 0.25 %
Sulfoxide Diastereomer-II	=< 0.25 %
Any unspecified impurity	=< 0.08 %
Total impurities	=< 1.0 %
Monohydroxy impurity	=< 3.0 %
Acid content	
Trifluoroacetic acid	=< 0.25 %
Acetic acid	=< 0.50 %
Gamma Cyclodextrin	=< 0.08 %
Assay	
Sugammadex Sodium	95.0 - 102.0 %
Sugammadex Sodium + monohydroxy impurity	98.0 - 102.0 %
Residual solvents [In-house]	
Methanol	=< 3000 ppm
Tetrahydrofuran	=< 720 ppm
Methylene Chloride	=< 600 ppm
Toluene	=< 890 ppm
tert-butyl methyl ether	=< 5000 ppm
Ethyl acetate	=< 5000 ppm
Dimethylformamide	=< 880 ppm
Dimethyl Sulfoxide	=< 5000 ppm
Sodium	7.5 - 9.2 %
Bacterial endotoxines	=< 0.15 EU/mg
Microbiological control	

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ATTRIBUTES	SHOULD BE
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absence/1g
Staphylococcus aureus	Absence/1g
Pseudomonas aeruginosa	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Preserve in tight, light-resistant containers.

REMARKS

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

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.