



SUGAMMADEX SODIUM

PRODUCT CODE: 151409

CAS Nº: 343306-79-6

ANALYSIS Nº: 281/23

MANUFACTURER BATCH: 4041/3/002/22

CERTIFICATE ID: 40.198

SUPPLIER BATCH: ----

MANUFACTURING DATE: 18/02/2022

METAPH BATCH: 0161123

RETEST DATE: 17/02/2027

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 %	6.5 %
Solution color		
Absorbance 430 nm	=< 0.05	0.001
Clarity of solution	Clear	Clear
pH	7.0 - 9.5	9.0
Related substances		
Sulfoxide Diastereomer-I	=< 0.25 %	0.09 %
Sulfoxide Diastereomer-II	=< 0.25 %	0.14 %
Any unspecified impurity	=< 0.08 %	< 0.08 % (#)
Total impurities	=< 1.0 %	0.31 %
Monohydroxy impurity	=< 3.0 %	0.5 %
Acid content		
Trifluoroacetic acid	=< 0.25 %	Not Detected
Acetic acid	=< 0.50 %	0.10 %
Gamma Cyclodextrin	=< 0.08 %	< 0.022 %
Assay		
Sugammadex Sodium	95.0 - 102.0 %	97.9 %
Sugammadex Sodium + monohydroxy impurity	98.0 - 102.0 %	98.4 %
Residual solvents [In-house]		
Methanol	=< 3000 ppm	588 ppm
Tetrahydrofuran	=< 720 ppm	< 50 ppm
Methylene Chloride	=< 600 ppm	< 40 ppm (*)
Toluene	=< 890 ppm	< 5 ppm (*)
tert-butyl methyl ether	=< 5000 ppm	< 13 ppm (*)
Ethyl acetate	=< 5000 ppm	< 50 ppm
Dimethylformamide	=< 880 ppm	140 ppm
Dimethyl Sulfoxide	=< 5000 ppm	Not Detected
Sodium	7.5 - 9.2 %	7.5 %
Bacterial endotoxines	=< 0.15 EU/mg	< 0.15 EU/mg (*)
Microbiological control		
TAMC	=< 1000 CFU/g	40 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: 17/01/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000993

**SUGAMMADEX SODIUM**

PRODUCT CODE: 151409		CAS Nº: 343306-79-6	ANALYSIS Nº: 281/23
MANUFACTURER BATCH:	4041/3/002/22	CERTIFICATE ID:	40.198
SUPPLIER BATCH:	----	MANUFACTURING DATE:	18/02/2022
METAPH BATCH:	0161123	RETEST DATE:	17/02/2027

Salmonella

Absence/1g

Absence/1g

COMPLIES WITH

Manufacturer Specifications

REMARKS

(#) Unspecified impurities detailed underneath:

RT (19.86 min) = 0.01 %

RT (24.40 min) = 0.03 %

RT (27.09 min) = 0.01 %

RT (30.99 min) = 0.02 %

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 manufacturer's certificate of analysis.

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.

Analysis date: 17/01/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000993