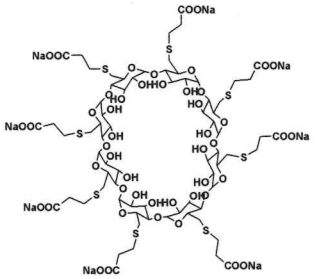
SPINCOTECH PVT LTD, *R&D Centre*
Shed No.B-21, SIDCO Pharmaceutical complex
Alathur, Thiruporur, Chennai - 603 110
Ph: 044-27444415; Mobile: 9384833003
E-mail: info@spincosynthesis.com
Web: www.spincosynthesis.com

CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT/ IMPURITY (IUPAC Name)	**SUGAMMADEX SODIUM** IUPAC NAME: Octakis(6-S-(2-carboxyethyl)-6-thio)cyclomaltooctaose octasodium salt

			STRUCTURE
CAS. No.	:	343306-79-6	
BATCH No.	:	SRD/0473/SUG-SOD/2023/01/01	
MFG. DATE	:	MAR-2023	
AR No.	:	SRD/0473/SUG-SOD/2023/01/01/AR23-0967	
DATE OF ANALYSIS	:	02 MAR 2023	
RETEST DATE	:	01 MAR 2024	
GRADE	:	IN-HOUSE	
BATCH QUANTITY	:	200 mg	



$C_{72}H_{104}Na_8O_{48}S_8$
Exact Mass: 2176.26

S. No.	TESTS	SPECIFICATIONS	RESULTS
1	Description	Report the result	White solid
2	Identification by MS	The exact mass of Sugammadex Sodium should be confirmed as 2000Da	Mass spectral data confirms the exact mass of Sugammadex Sodium as 2000Da
3	Identification by ^{1}H & ^{13}C NMR	The molecular structure of Sugammadex Sodium should be confirmed by ^{1}H & ^{13}C NMR spectra	^{1}H & ^{13}C NMR spectra confirms the molecular structure of Sugammadex Sodium
4	Water content by KF	For informative	6.68% w/w
5	Purity by HPLC	For Informative	99.25% Area
6	Volatile loss by TGA	For Informative	4.72 w/w
7	Potency	For Informative	94.53% w/w

Storage condition: (i) For long term: Storage at 2 to 8°C.
(ii) For transport: Ambient temperature.

Remarks: The product **conforms / does not conform** to the above specification.

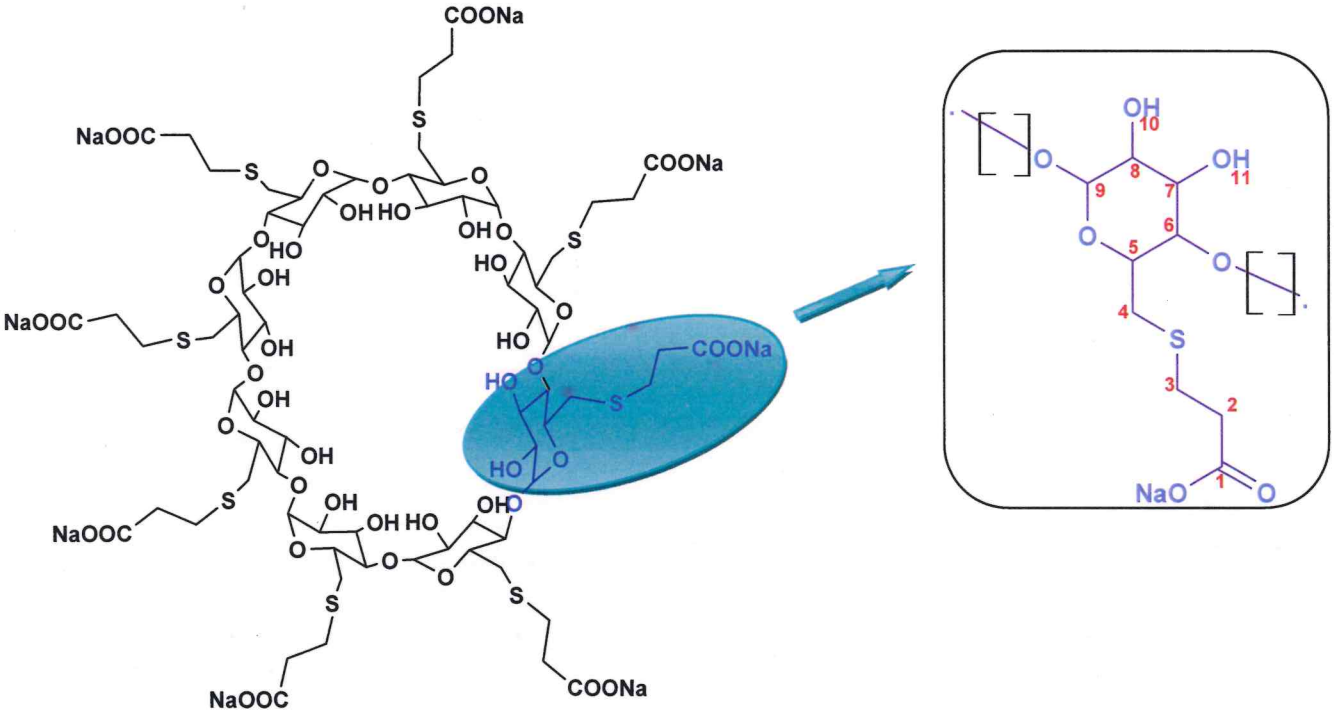
Prepared By (Sign& Date)	A. Stanislas 08 Mar 2023	Reviewed By (Sign& Date)	08 mar 2023	Approved By (Sign& Date)	09 Mar 23

^{1}H & ^{13}C NMR Spectral data

Conditions: 200 MHz, D_2O

The structure of Sugammadex Sodium (SRD/0473/SUG-SOD/2023/01/01) is matching with the signals of the ^{1}H & ^{13}C NMR spectra and their respective interpretation.

Sugammadex Sodium



$C_{72}H_{104}Na_8O_{48}S_8$
Exact Mass: 2176.26

The assignment of ^{1}H and ^{13}C NMR signals of Sugammadex Sodium

Position [a]	^{1}H	^{1}H δ(ppm)	Multiplicity [b]	^{13}C δ(ppm)	^{13}C
1	--	--	--	180.544	COOH
2	16H	2.375-2.448	t	33.146	CH_2
3	16H	2.745-2.818	t	29.360	CH_2
4	16H	2.857-3.093	m	37.544	CH_2
5	8H	3.508-3.575	m	72.558	CH
6	8H	3.946-3.975	m	71.042	CH
7	8H	3.798-3.892	t	72.346	CH
8	8H	3.508-3.575	m	82.573	CH
9	8H	5.062-5.079	d	101.240	CH
10 [c]	8H	--	--	--	OH
11 [c]	8H	--	--	--	OH

[a] Carbon and hydrogen numbering only NMR spectral data assignments,

[b] ***Resonance multiplicities, coupling constants, and coupled partners in parentheses***: (***d***) doublet, (***t***) triplet, (m)multiplet.

[c] Labile protons got exchanged with ***D_2O*** NMR solvent in the ^{1}H NMR spectrum.

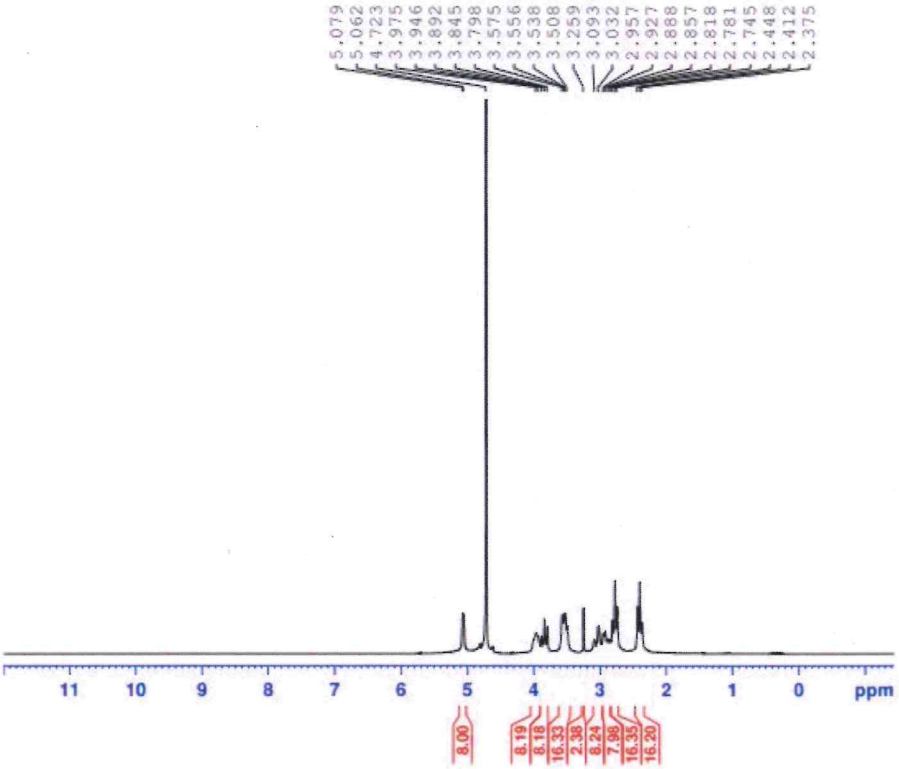
Note: Trace of residual solvent of Methanol observed in the proton NMR spectrum.

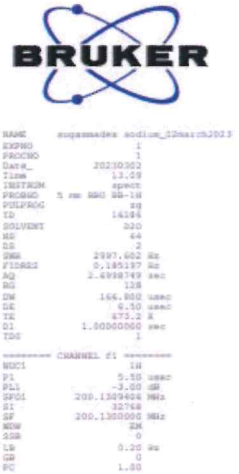
A. Stanislas 08 Mar 2021

08 Mar 2021

^{1}H NMR spectrum of Sugammadex Sodium

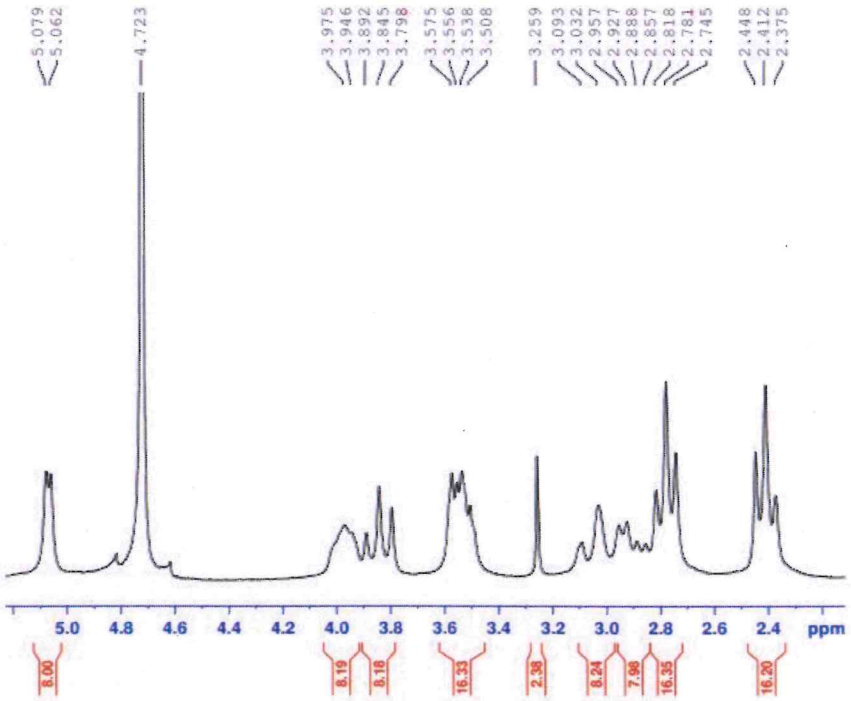
B.No: SRD/0473/SUG-SOD/2023/01/01

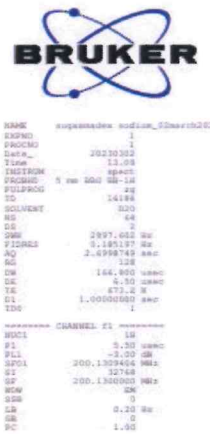




^{1}H NMR spectrum of Sugammadex Sodium (Zoomed 1)

B.No: SRD/0473/SUG-SOD/2023/01/01





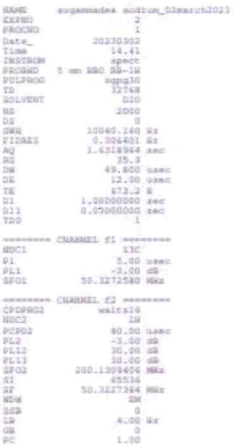
A. Sharief
08 Mar 2023

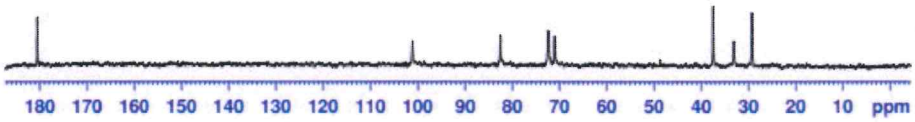
08 MAR 2023

^{13}C NMR spectrum of Sugammadex Sodium

B.No: SRD/0473/SUG-SOD/2023/01/01

BRUKER





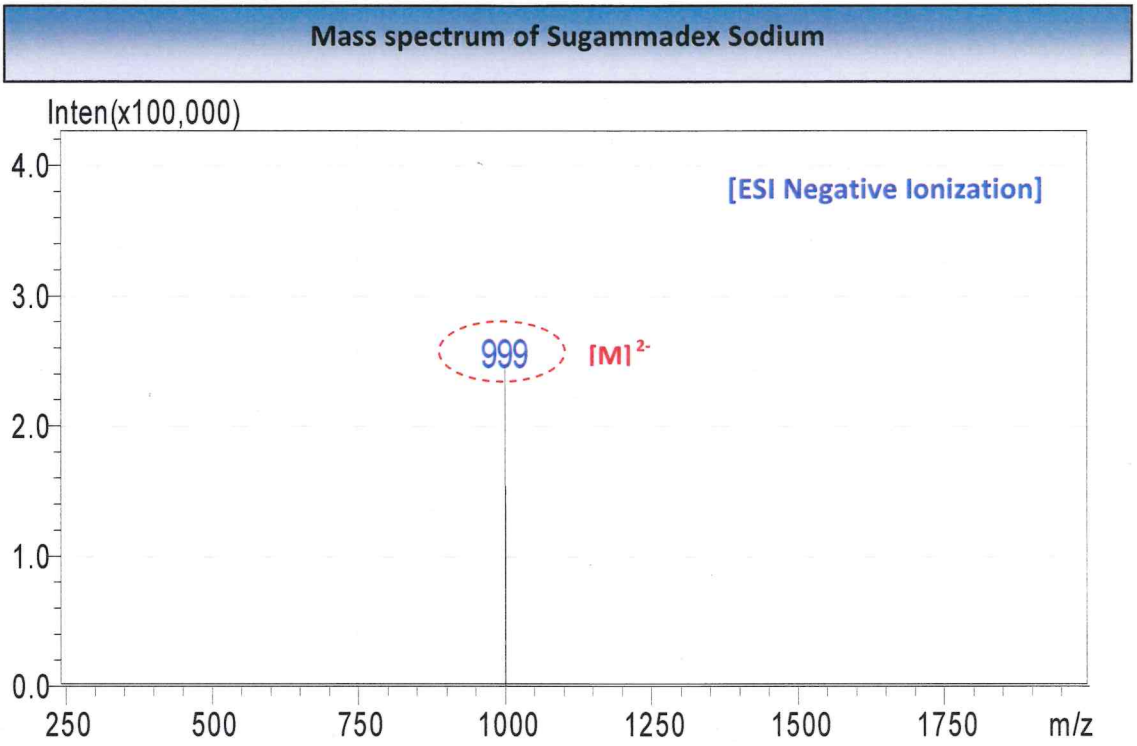
A. Ganesh
08 Mar 2023

08 mar 2023

Mass Spectral data

Method conditions: ESI 3.5kV Negative DL temperature 230°C

The exact mass of Sugammadex Sodium (SRD/0473/SUG-SOD/2023/01/01) is confirmed as 2000Da (Seen as m/z 999(-ve) $[M]^{2-}$ di-charged ion) by the signals of ESI mass spectral data.



A. Stanislaus
08Mar2023

08 mar 2023

Labindia

Automatic Karl Fischer Titrator

SPINCOTECH PVT. LTD, THIRUPORUR.

S/W : V6.0.0 H/W : V7.33

Identification No. : Sugammadex Sodium Trial-1 03/03/2023 15:08:27 #9

KF TITRATION ANALYSIS REPORT

Batch Number	AR23-0967/GLP-AR23-0066
Instrument Sr. No.	KS21060210
Burette Size	10 ml
Burette Factor	1.0
Run Time (hh:mm:ss)	00:01:32
Result Status	
Review Remark	
Approve Remark	

METHOD PARAMETERS

Method Name	% Moisture Content
Sample Name	Water
Titrant Name	KF Reagent
Titration Type	Water Determination
Titration Mode	Minimum Dose & Delay

SAMPLE ANALYSIS PARAMETERS

Stir time	30 sec
Minimum Dose	10 ul
Delay	30 sec
Initial mv	523.00 mV
Current Setting	16.0 uA

CALCULATION PARAMETERS

Concentration	4.8704 mg/ml
Sample Weight	100.86 mg (M)
Leak Volume	0.0 ml

KF TITRATION RESULT

Run No.1

Total Volume Disp. : 1.360 ml

Tester Reviewer Approver

Kannan S

Analysis done on LABINDIA Auto Titrator

Printed On : 06-03-2023 11:14:31 page 1 Printed By : admin

A. Harish 08 Mar 2023

08 Mar 2023

Labindia

Automatic Karl Fischer Titrator

SPINCOTECH PVT. LTD, THIRUPORUR.

S/W : V6.0.0 H/W : V7.33

Identification No. : Sugammadex Sodium Trial-1 03/03/2023 15:08:27 #9

Result : 6.5673 %

Tester
Kannan S

Reviewer

Approver

Analysis done on LABINDIA Auto Titrator

Printed On : 06-03-2023 11:14:31 page 2 Printed By : admin

A. Stanislaus
08 Mar 2023

1.3.23

Labindia

Automatic Karl Fischer Titrator

SPINCOTECH PVT. LTD, THIRUPORUR.

S/W : V6.0.0 H/W : V7.33

Identification No. : Sugammadex Sodium Trial-2 03/03/2023 15:24:23 #11

KF TITRATION ANALYSIS REPORT

Batch Number	AR23-0967/GLP-AR23-0066
Instrument Sr. No.	KS21060210
Burette Size	10 ml
Burette Factor	1.0
Run Time (hh:mm:ss)	00:01:32
Result Status	
Review Remark	
Approve Remark	

METHOD PARAMETERS

Method Name	% Moisture Content
Sample Name	Water
Titrant Name	KF Reagent
Titration Type	Water Determination
Titration Mode	Minimum Dose & Delay

SAMPLE ANALYSIS PARAMETERS

Stir time	30 sec
Minimum Dose	10 ul
Delay	30 sec
Initial mv	547.00 mV
Current Setting	16.0 uA

CALCULATION PARAMETERS

Concentration	4.8704 mg/ml
Sample Weight	101.18 mg (M)
Leak Volume	0.0 ml

KF TITRATION RESULT

Run No.1

Total Volume Disp. : 1.413 ml

Tester Reviewer Approver

Kannan S

Analysis done on LABINDIA Auto Titrator

Printed On : 06-03-2023 11:13:48 page 1 Printed By : admin

A. Stanley 08 Mar 2023

07 Mar 2023

Labindia

Automatic Karl Fischer Titrator

SPINCOTECH PVT. LTD, THIRUPORUR.

S/W : V6.0.0 H/W : V7.33

Identification No. : Sugammadex Sodium Trial-2 03/03/2023 15:24:23 #11

Result : 6.8016 %

Tester Reviewer Approver

Kannan S

Analysis done on LABINDIA Auto Titrator

Printed On : 06-03-2023 11:13:49 page 2 Printed By : admin

Observation:

Moisture content = 6.68% w/w

A. Stanley 06 Mar 2023

06 Mar 2023

Purity by HPLC

The purity of Sugammadex sodium is analyzed by HPLC using In-house method

Purity : 99.25% Area

Attached the HPLC chromatogram

Blank

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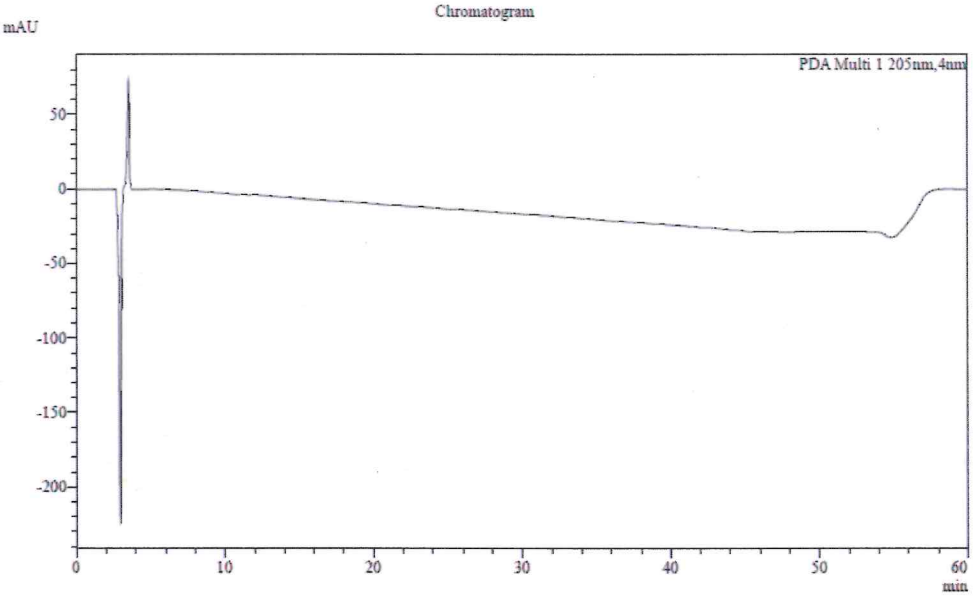
Sample Information

Acquired by	: Manikandan R
Sample Name	: Blank
Sample ID	:
Tray#	: 1
Vial#	: 1
Injection Volume	: 30
Data File	: SPL-GIC-006_0203001.lcd
Method File	: Sugammadex HPLC method.lcm
Batch File	: Sugammadex sodium_Purity_SPL-GIC-006_020323.lcb
Date Acquired	: 3/2/2023 4:07:06 PM
Date Processed	: 3/2/2023 5:21:42 PM
Processed by	: Manikandan R

Chromatogram



Peak Table

PDA Ch1 205nm

Peak#	Name	Ret. Time	Area	Area%
Total				

A. Stanirl 08 Mar 2023

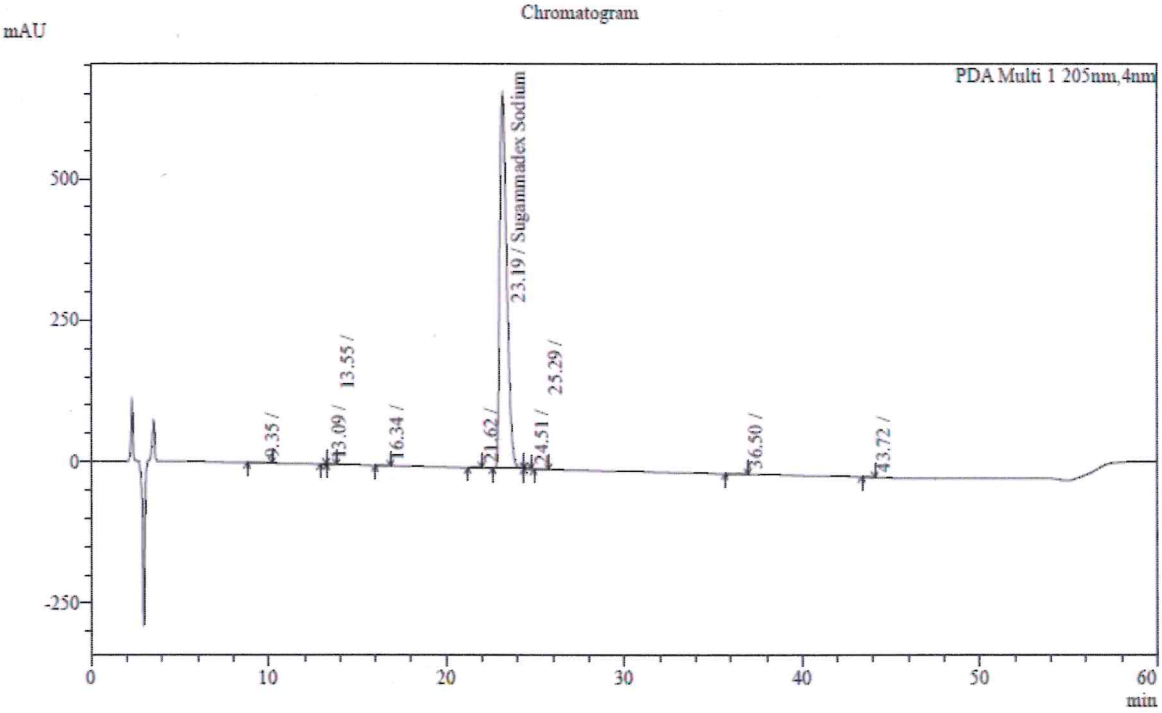
08 mar 2023

SPINCOTECH PVT LTD
ALATHUR.

Sample Information

Acquired by	: Manikandan R
Sample Name	: Sugammadex Sodium_Preparation 1
Sample ID	: AR23-0967/GLP-AR23-0066
Tray#	: 1
Vial#	: 3
Injection Volume	: 30
Data File	: SPL-GIC-006_0203004.lcd
Method File	: Sugammadex HPLC method PM.lcm
Batch File	: Sugammadex sodium_Purity_SPL-GIC-006_020323.lcb
Date Acquired	: 3/2/2023 8:51:56 PM
Date Processed	: 3/3/2023 12:18:14 PM
Processed by	: Manikandan R

Chromatogram



Peak Table

PDA Ch1 205nm

Peak#	Name	Ret. Time	Area	Area%
1		9.35	20423	0.11
2		13.09	1285	0.01
3		13.55	11567	0.06
4		16.34	14384	0.08
5		21.62	26071	0.14
6	Sugammadex Sodium	23.19	18146948	99.25
7		24.51	1440	0.01
8		25.29	15772	0.09
9		36.50	28298	0.15
10		43.72	17861	0.10
Total			18284050	100.00

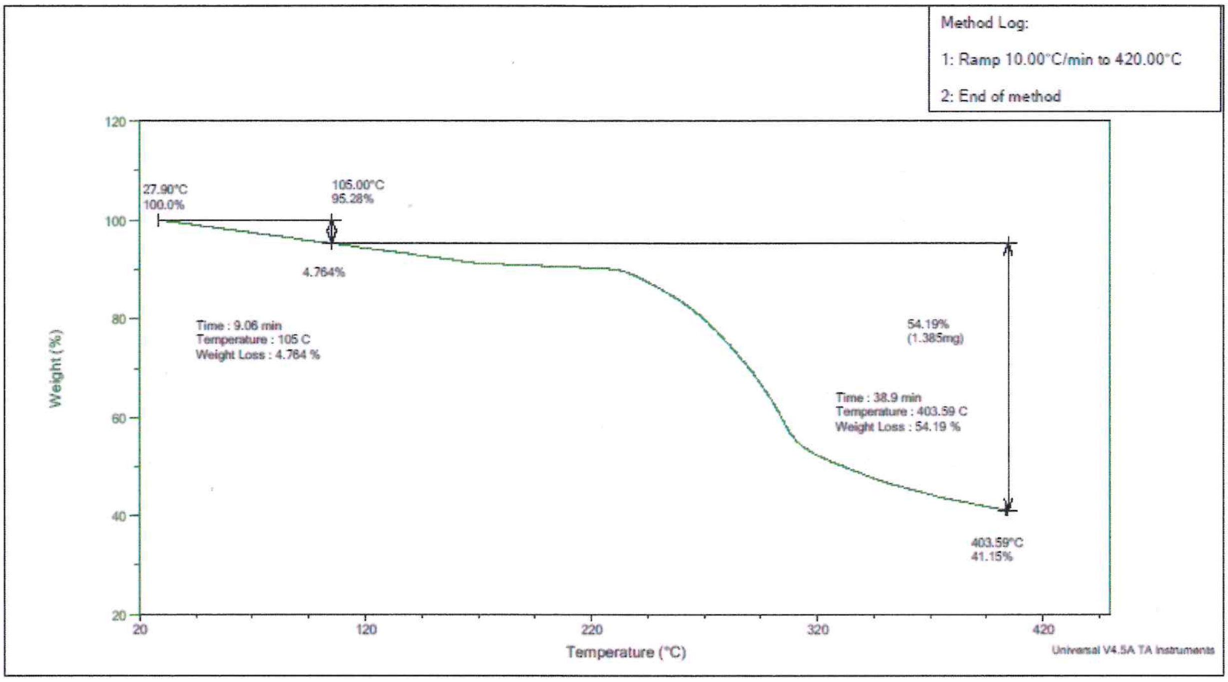
A. Stanislaus 08 Mar 2023

07 mar 2023

Volatile Loss Analysis by Thermogravimetry (TGA)

Sample Name: Sugammadex Sodium

Batch No. : SRD/0473/SUG-SOD/2023/01/01



Volatile loss Calculation:

Volatile loss: Initial percentage – percentage after volatile loss

= 100-95.28%

= 4.72% w/w

Percentage of Volatile loss = 4.72% w/w

A·Daniel 08 Mar 2023

08 mar 2023

Impurity Potency Calculation

Sample Name: Sugammadex Sodium
Batch No. : SRD/0473/SUG-SOD/2023/01/01

Potency Calculation:

Potency : Purity – Percentage of volatile loss

= 99.25% -4.72% w/w

= 94.53% w/w

Potency = 94.53% w/w

A. Stanley 08 MAY 2023

08 MAY 2023