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Analytical Method Verification and Optimization of an Assay of Sugammadex Sodium API by RP-HPLC

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Abstract The foundation of High Performance Liquid Chromatography (HPLC) is the affinity principle. In pharmaceutical enterprises and laboratories, the HPLC technology was utilized to separate the API and excipients and determine their purity and quantity. One of the most sophisticated methods in the current world is HPLC, which uses two analytical techniques: qualitative analysis and quantitative analysis. In the HPLC, the mobile phase and stationary phase play the most important roles. Natural interactions between the solute and stationary phase can result from a variety of forces, including electrostatic, vanderwall, hydrophobic and hydrogen bonding forces, among others. The chromatographic representation should be utilized to identify the result. The different detectors employed in HPLC include mass spectrometer, photodiode array detectors, UV-visible detectors and refractive index detectors. Both polar and non polar compounds are present in these two phases, which are the reverse phase and normal phases. Affinity decreases result in polar to polar and non-polar-to-non- polar interactions. However, the increase in affinity is caused by the polar to non polar interaction.

Method: Using Shimadzu's isocratic program and instrumentation, the process was optimized for the assay of Sugammadex. a C18,4.6 x 250 mm 5µm Waters symmetry column equipped with a UV detector with a wavelength of 254 nm.

Results: The Optimize of method of Sugammadex API in accordance with the ICH Q2R(1) guideline. The assay result were found to be 1.756% was observed within the limit of <2.0%.

Keywords: API, HPLC.

Introduction

It is selective relaxant binding agent that is modified gamma cyclodextrin. Chemical name is 6-per-deoxy-6per-(2-carboxyethyl) thio-gamma)-cyclodextrin, Sodium salt. That they have complex structure but required extremely polarity and good water solubility. Sugammadex Sodium is brand name bridion. Neuromuscular blocking agent of Vecuronium bromide & rocuronium bromide. It is especially used for ventilation, general anaesthesia (or) otherwise used tracheal intubation of patient may surgery. It is inclusion of some complex is maintained by combination of intermolecular Van der walls forces, Hydrogen bonds, hydrophobic interaction etc… This agent are required by crucial for maintain Stable Surgical field that prevent involuntary muscle movements, and also the precision and safety required. The use NMBA that is not without risk should be residual & blockade can result in respiratory complication, impaired airway reflexes, delayed recovery & clinical management challenges, para sympathetic side effect is undesirable (or) unidentified. Para Sympathetic side effect Such as the Neuromuscular Junction, Neostigmine is routinely co-administered with anticholinergic agent. If cause adverse effect included urinary retention, delayed gastrointestinal recovery (or) tachycardia. The clinical advantages of Sugammadex optimal used specific patient populations, including the renal impairment, obesity, obstetric & paediatric setting. Mechanism of action of sugammadex was first enter the plasma & it encapsulates the circulating amino steroid rendering it inactive. Secondly, it promotes the in to dissociation of the amino steroid from the Neuromuscular Junction (NMJ) by created a concentration gradient from NMJ of the plasma to be encapsulated. The Sugammadex in also diffuses out the plasma extracellular fluid compartment, encapsulating any unbound amino steroid it encounters. It causes some side effects & Precautions included: Hypersensitivity, Coagulation, Arrhythmias, and Neurotoxic.

Common Side effect: Dysgeusia, headache, fatigue, urticaria, Nausea, Vomiting, dizziness, and abdominal pains. Structure:It haseight glucopyranoside unit, linked via alpha 1→4 linkage to maintain a doughnut like shape. The Negatively charged OH group at aims create the 1°C and secondary (2) faces. The water solubility of the molecules responsible. The linked by carbon atoms, which the alpha 1→4 linkages create the Core.

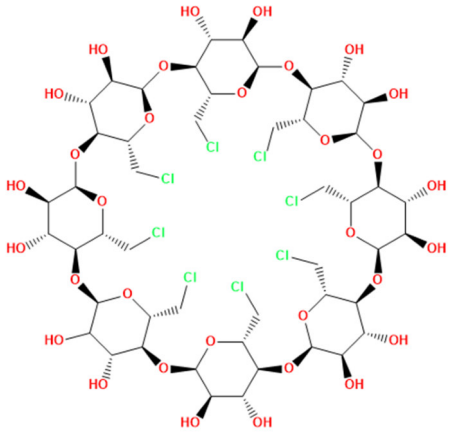


Fig.1 Sugammadex structure

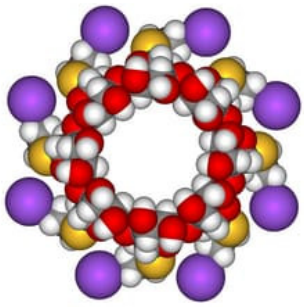


Fig 2: 3D Structure

HPLC INTRODUCTION

High Performance liquid chromatography (HPLC) that is also called as High Pressure Liquid Chromatography is one type of the column chromatography, is commonly used in biochemistry and analysis to separate, identify and quantify active chemicals.HPLC is accurate method is widely used for quantitative & qualitative analysis.If they included the two phases then mobile phase and stationary phase.HPLC have some principle used for separation that is affinity chromatography, adsorption chromatography, size exclusion, ion-exchange chromatography & chiral phase chromatography.Column due to the gravity used normally flow that through the solvent.Sample separate that is used in 400 atmospherespressure than have relative pressure.The stationary phase is pump through the mobile phase of the sample.It is affect the chemical (or) physical interaction occur on the mobile phase & stationary phases.They affected by the retention time at the interaction of the molecules.HPLC is used to have two elution techniques one is the isocratic elution that maintain a constant mobile phase another one is the gradient elution that involves continuous alteration ot the mobile phase. They identify the solvent strength, constant, analytical time, run

time and reproducibility. They occurs interaction between the solute and stationary phase that may arises from the hydrogen bonding, vander waals forces, electrostatic forces etc…

They have Van Deemter equation = A+B/μ+Cμ

A. Eddy diffusion
B. Longitudinal diffusion
C. Concentration
D. μ- Concentration μ- Linear Viscosity

A solvent resrvoir, apump an injection valve,a column, a detector unit, data processing unit is present in HPLC system.

The different types of HPLC is included the normal phase, reverse phase, size exclusion, Ion-exchamge. The mixture that contain greater separation of the compound. HPLC is based upon the affinity chromatography that contain non-polar stationary phase, polar mobile phase. The compound have the less affinity toward stationary phase travel flow faster. They have different detectors included. Some of the like that Mass spectrometer, UV- visible detector, Photodiode array detector and Refractive index detector.

Aim and objective

The aim of this study is to optimize the method of assay of the sugammadex sodium API and verification of the analytical method parameters.

Materials and methods

Instrumentation

Table 1: Instrumentation

Name of the Instrument	Make/Model
HPLC System	Shimadzu
Analytical Balance	Sartorius
pH meter	PICO+
Vacuum oven	Lab India
Column	Waters Symmetry C18,4.6x250 mm, 5μm in diameter

Chemicals and Reagents

Chemical and reagents like dibasic ammonium hydrogen phosphate, ortho phosphoric acid, Acetonitrile and water were used in HPLC grade throughout the Experiment.

Chromatographic Conditions

Table 2: Chromatographic conditions

Column	Waters , 250 mm x 4.6mm, 5μm diameter
Detector	UV, 254 nm
Flow rate	1.0mL/min
Injection volume	10μL
Column oven temperature	25 °C
Run time	15 minutes
Auto sampler temperature	5°C

Preparations of Solutions

Mobile phase:

Preparation of Buffer:

Prepare a mixture of 2.68g of dibasic Ammonium hydrogen phosphate in 1000 mL water. Adjust the pH of 3.0 using Orthophosphoric acid and make the volume with water.

Preparation of mobile phase:

Prepare a mixture of Buffer and Acetonitrile as 30:70. Filter and degas. For 3000ml of mobile phase mix 900 of Buffer and 2100mL of Acetonitrile, and sonicated it for degas.

Diluent:

Mobile phase will be used as diluents.

Standard solution:

Weigh accurately about 10.0 mg of Sugammadex reference / working standard in to a 100 mL volumetric flask, dissolve and make up to the mark with mobile phase. (Prepare a 0.1mg/mL of Sugammadex in mobile phase).

Sample solution:

Weigh accurately about 10.0 mg of Sugammadex sample in to a 100 mL volumetric flask, dissolve and make up to the mark with mobile phase. (Prepare a 0.1mg/mL of Sugammadex in mobile phase).

Method verification

As per the ICH guidelines all the method has been verified and finds all the test result are complied within the standard results. The following parameters of analytical methods are verified for the assay of sugammadex sodium API,

- System suitability
- Specificity
- Precision
  - System Precision
  - Method Precision(Repeatability)
- Linearity
- Accuracy

System suitability

To verify that the analytical system is working properly and can give accurate and precise results, the system suitability parameters are to be set. Equilibrate the column and system for half an hour at the initial flow rate. Inject exactly 10 μL of diluent (1 injection) in to the system and record the chromatogram for 15

minutes as a blank. Inject 10 µL of standard solution (5 injections) in to the system separately and verify the system suitability parameters.

Specificity

It is one of the parameter used to identify the minimum quantity of the analyte that may be expected to be present in the sample like API, Excepients, impurities, degradation products etc. Inject exactly 10 µL of each blank, standard and sample solution in to the system separately. Record the retention time of Sugammadex peak and peak interference of the blank at the retention time of Sugammadex by comparing the blank and standard chromatograms.

Precision

The precision of an analytical method is the degree of agreement among individual test results when the method is applied repeatedly to multiple sampling of homogeneous sample .The precision of analytical method is usually expressed as the standard deviation or relative standard deviation (Coefficient of variation) of series of measurements.

- System Precision
- Method Precision(Repeatability)

System Precision

The system precision shall be checked by using standard chemical substance to ensure that the analytical system is working properly. The retention time and area response of six determinations should be measured and calculate relative standard deviation. Inject 10 µL of Blank and Standard solution for six times. Record the chromatogram and calculate the relative standard deviation.

Method Precision (Repeatability)

In method precision, a homogeneous sample of a single batch should be analyzed six times. This indicates whether a method is giving consistent results of a single batch. The preparation of blank, standard solution and sample solution (six preparations) to be following as per the procedure given in the methodology section and inject into the chromatographic system as below procedure. Analyse the sample of Sugammadex sample six times of a same batch as per analytical procedure. Calculate the % Assay and % RSD from the six sample preparation.

Linearity

The Linearity of an analytical method is its ability to find out the test results that are directly proportional to the concentration of analyte in samples within a given range. Prepare the blank and standard solutions as described in the methodology section. Perform the linearity for Sugammadex standard in the range of 50% to 150% of working standard concentration.

Linearity Stock Solution:

Weigh accurately about 50 mg of Sugammadex Working Standard in to a 20 mL volumetric flask, dissolve and make up the volume with mobile phase.

Linearity-50% level Solution Preparation:

Pipette 1.0 mL linearity stock solution in to a 50mL volumetric flask, dissolve and make up the volume with mobile phase.

Linearity-75% level Solution Preparation:

Pipette 1.5 mL linearity stock solution in to a 50mL volumetric flask, dissolve and make up the volume with mobile phase.

Linearity-100% level Solution Preparation:

Pipette 2.0 mL linearity stock solution in to a 50mL volumetric flask, dissolve and make up the volume with mobile phase.

Linearity-125% level Solution Preparation:

Pipette 2.5 mL linearity stock solution in to a 50mL volumetric flask, dissolve and make up the volume with mobile phase.

Linearity-150% level Solution Preparation:

Pipette 3.0 mL linearity stock solution in to a 50mL volumetric flask, dissolve and make up the volume with mobile phase.

Accuracy

The accuracy of an analytical method is the closeness of test results obtained by that method to the true value (Standard value). Prepare the Sugammadex standard at 50%, 100%, and 150% of working concentration in triplicate. Analyse this sample in triplicate for each level. From the results, calculate the mg of Sugammadex for each level.

Accuracy-50% level Solution Preparation:

Weigh accurately about 5.0 mg of Sugammadex sample in to a 100 mL volumetric flask, dissolve and make up to the mark with mobile phase. (Prepare a 0.05mg/mL of Sugammadex in mobile phase).

Accuracy-100% level Solution Preparation:

Weigh accurately about 10.0 mg of Sugammadex sample in to a 100 mL volumetric flask, dissolve and make up to the mark with mobile phase. (Prepare a 0.05mg/mL of Sugammadex in mobile phase).

Accuracy-150% level Solution Preparation:

Weigh accurately about 15.0 mg of Sugammadex sample in to a 100 mL volumetric

flask, dissolve and make up to the mark with mobile phase. (Prepare a 0.05mg/mL of Sugammadex in mobile phase).

Calculation:

Calculate the Sugammadex in mg by using the below calculation

$$\text{Sugammadex in mg} = \frac{AT}{AS} \times \frac{WS}{DS} \times \frac{DT}{V} \times \frac{P}{100} \times 100$$

Where,

AT: Average area response of Sugammadex peak from the chromatogram of sample preparation

AS: Average area response of Sugammadex peak from the chromatogram of standard preparation

WS: Weight of Sugammadex standard taken in mg

DS: Dilution of standard Solution

DT: Dilution of Standard solution preparation

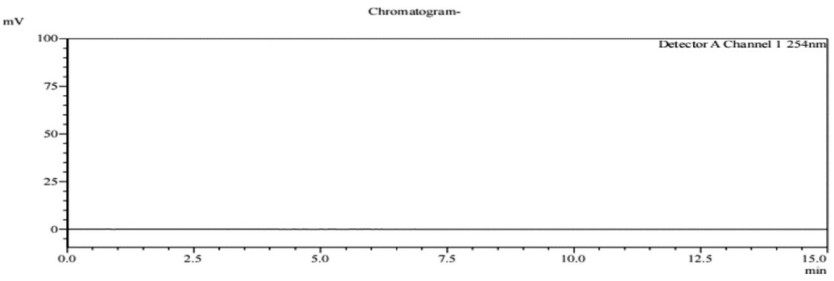
V: Volume of sample solution preparation

P: Potency of Sugammadex standard in % w/w on as is basis

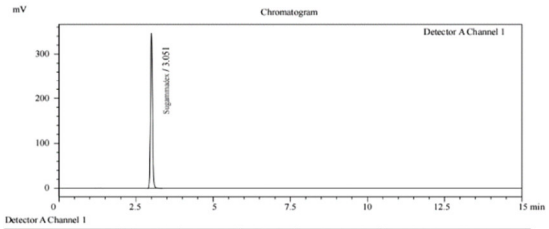
Result and discussion

The method has been optimized for the assay of sugammadex API by RP-HPLC. In this optimized method we are used the mobile phase of Buffer and Acetonitrile in the ratio of 30:70 for the separation of sugammadex with the P^H 3.0.The column used for the separation is Waters symmetry 250 mm x 4.6mm, 5µm diameter, UV detector at the wavelength of 254nm with the flow rate of 1.0mL/min.

System suitability

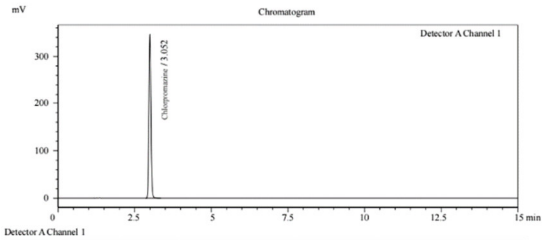


Chromatogram No.1 System suitability- Blank



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex Std	3. 051	3393521	100.00	1.17	5255

Chromatogram No.2 System suitability STD-1



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex Std	3. 052	3376157	100.000	1.17	5245

Chromatogram No.3 System suitability STD-2

Table 3: Area response of blank and five standard injections in HPLC for System suitability

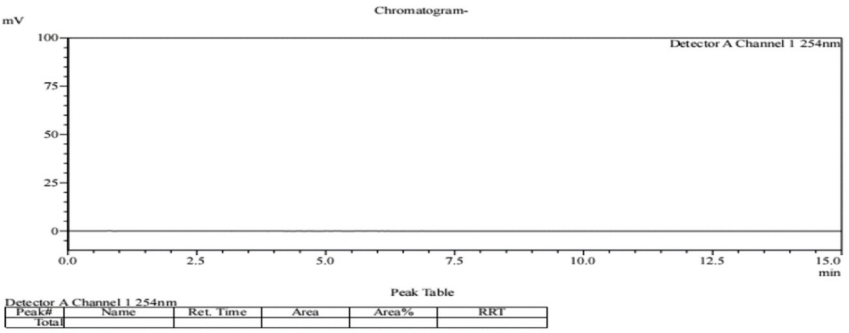
S. No	Name	Retention Time	Area	Tailing Factor	No. of Theoretical Plates
1	BLANK	-	-	-	-
2	STD SOLUTION 1	3.051	3393521	1.17	5255
3	STD SOLUTION 2	3.052	3376157	1.17	5245
4	STD SOLUTION 3	3.051	3372025	1.17	5151
5	STD SOLUTION 4	3.053	3373074	1.17	5247
6	STD SOLUTION 5	3.052	3384619	1.17	5193

Table 4: Results for System suitability parameter.

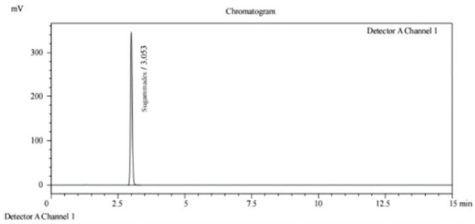
S. No	Acceptance Criteria	Result
1	Tailing factor for Sugammadex peak should be not more than 2.0	1.17
2	Theoretical plates for Sugammadex peak in standard Solution should be more than 2000	5300
3	RSD for Sugammadex peak in standard solution should not be more than 1.0%	0.02%

All the test results of the system suitability parameter are complies within the limits. The result found for the tailing factor was 1.17, theoretical plate count was 5300 and RSD of sugammadex was identified as 0.02%

Specificity

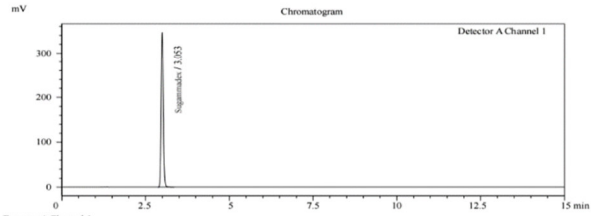


Chromatogram No.4 Specificity- Blank



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 053	3253554	100.00	1.17	5300

Chromatogram No.5 Specificity- STD



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 053	3253668	100.00	1.17	5288

Chromatogram No.6 Specificity- Sample

Table 5: Sequence of specificity

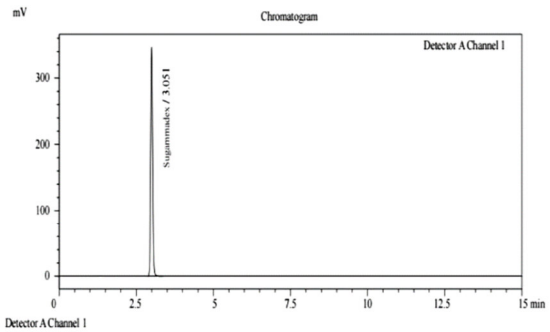
S. No	Solution details	No of injections
1	Blank (Diluent)	1
2	Standard solution	1
3	Sample solution	1

Acceptance criteria for specificity

Tailing there should be no interfering peaks in the chromatogram of the diluents at the retention time corresponding to the peak of Sugammadex. Here no interference were found of all the three injections. So the test result complies.

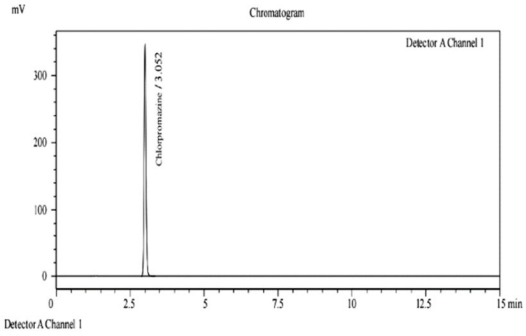
Precision

System precision



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex Std	3. 051	3393521	100.00	1.17	5255

Chromatogram No.7 System precision- STD-1



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex Std	3. 052	3376157	100.000	1.17	5245

Chromatogram No.7 System precision-STD-2

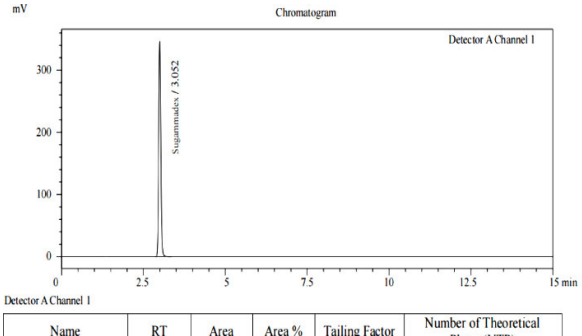
Table 6: Area response and Retention time of 5 standard injection for System precision

S. No	Name	Retention Time	Area
1	BLANK	–	–
2	STD SOLUTION 1	3.051	3393521
3	STD SOLUTION 2	3.052	3376157
4	STD SOLUTION 3	3.051	3372025
5	STD SOLUTION 4	3.053	3373074
6	STD SOLUTION 5	3.052	3384619

Table 7: Test results of the system precision

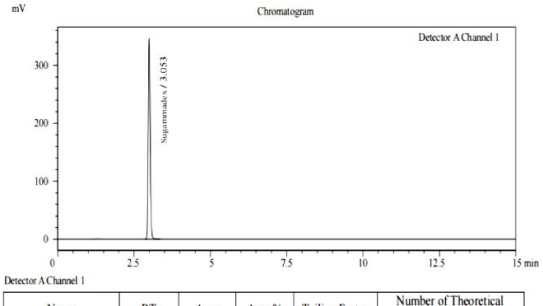
S. No	Acceptance Criteria	Results
1	The RSD of the Retention time for Sugammadex peak obtained from 6 injections of standard solution should be NMT 1.0%	0.02%
2	The RSD of the Area response for Sugammadex peak obtained from 6 injections of standard solution should be NMT 1.0%	0.27%

Method precision (Repeatability)



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex Spl	3. 051	3517889	100.000	1.17	5241

Chromatogram No.8 method precision-SPL-1



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex Spl	3. 053	3405439	100.000	1.17	5252

Chromatogram No.9 method precision-SPL-2

Table 8: Area response of blank, five standard injections and sample injection in RP- HPLC for method precision

S. No	Name	Retention Time	Area
1	BLANK	–	–
2	STANDARD SOLUTION 1	3.05	3393521
3	STANDARD SOLUTION 2	3.05	3376157
4	STANDARD SOLUTION 3	3.05	3372025
5	STANDARD SOLUTION 4	3.05	3373074
6	STANDARD SOLUTION 5	3.05	3384619
7	SAMPLE SOLUTION SET(1-A)	3.05	3517889
8	SAMPLE SOLUTION SET(1-B)	3.05	3405439
9	SAMPLE SOLUTION SET(2-A)	3.05	3409052
10	SAMPLE SOLUTION SET(2-B)	3.05	3309047
11	SAMPLE SOLUTION SET(3-A)	3.05	3329681
12	SAMPLE SOLUTION SET(3-B)	3.05	3275426
13	STD SOLUTION BKT 1	3.05	3285426
14	SAMPLE SOLUTION SET(4-A)	3.05	3254679
15	SAMPLE SOLUTION SET(4-B)	3.05	3256092
16	SAMPLE SOLUTION SET(5-A)	3.05	3378748
17	SAMPLE SOLUTION SET(5-B)	3.05	3345704
18	SAMPLE SOLUTION SET(6-A)	3.05	3249869
19	SAMPLE SOLUTION SET(6-B)	3.05	3265739
20	STD SOLUTION BKT 2	3.05	3385670

Assay Result

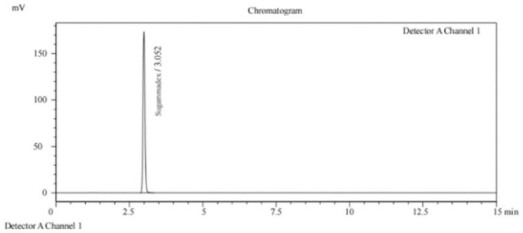
Table 9: Test results of Assay of Sugammadex Sodium API

S.No	NAME	RESULT
1	SAMPLE PREPARATION 1	100.37%
2	SAMPLE PREPARATION 2	100.30%
3	SAMPLE PREPARATION 3	100.54%
4	SAMPLE PREPARATION 4	100.44%
5	SAMPLE PREPARATION 5	100.69%
6	SAMPLE PREPARATION 6	100.60%

Assay procedure is used to find out/determine the amount of API present in the given sample.From the above table 9 we can conclude that the assay of sugammadex API is found within the standard limits 98%-102%. The RSD calculated on 6 determinations for Sugammadex API is also complies

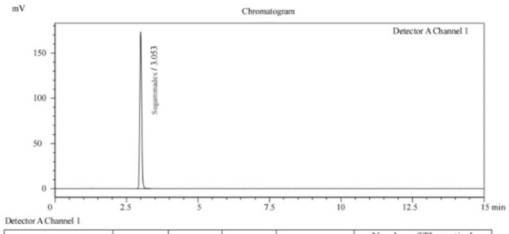
Linearity

A linear correlation was obtained between the peak area used and concentrations of sugammadex. The calibration curve was linear for concentrations between 50 and 150µg/ml. The linearity of the calibration curves was validated by the values of the regression correlation coefficients (r2). The correlation coefficient was found to be 0.999.



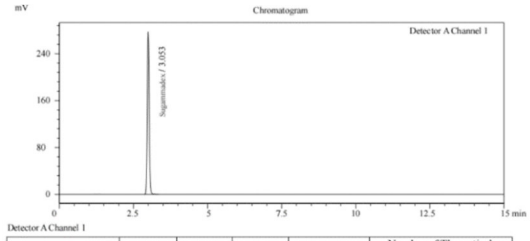
Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 052	1651985	100.000	1.17	5250

Chromatogram No 10-Linearity at 50% level-1



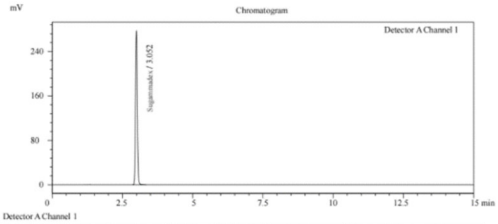
Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 053	1667668	100.000	1.17	5242

Chromatogram No 11-Linearity at 50% level-2



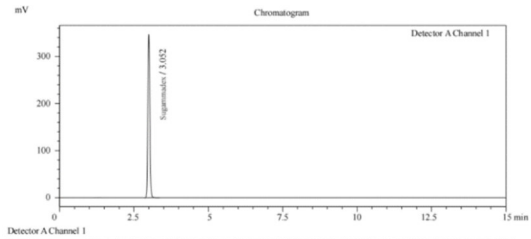
Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 053	2493691	100.000	1.17	5244

Chromatogram No 11-Linearity at 75% level-1



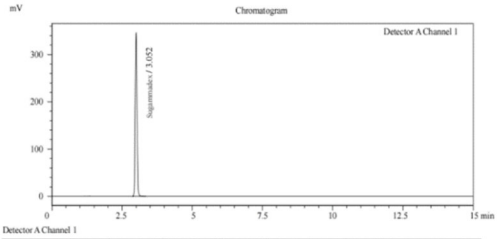
Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 052	2524417	100.000	1.17	5241

Chromatogram No 12-Linearity at 75% level-2



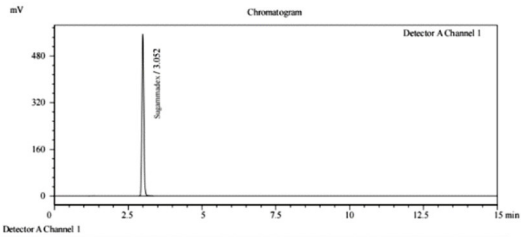
Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 052	3315024	100.000	1.17	5245

Chromatogram No 13-Linearity at 100% level-1



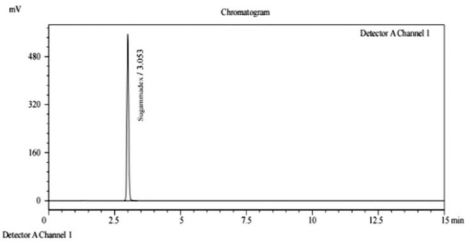
Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 052	3317467	100.000	1.17	5238

Chromatogram No 14-Linearity at 100% level-2



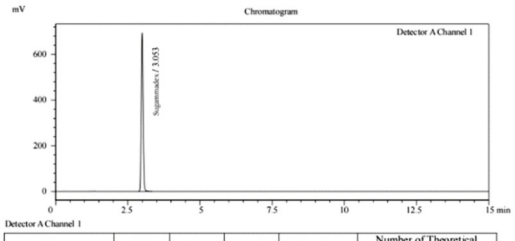
Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 052	4145138	100.000	1.17	5250

Chromatogram No 15-Linearity at 125% level-1



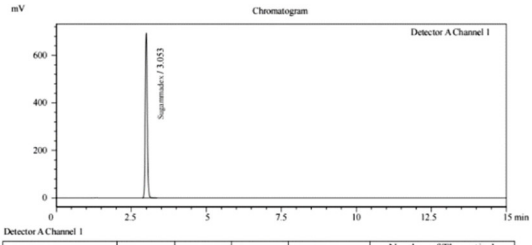
Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 053	4146295	100.000	1.17	5243

Chromatogram No 16-Linearity at 125% level-2



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 053	4939117	100.000	1.17	5249

Chromatogram No 17-Linearity at 150% level-1

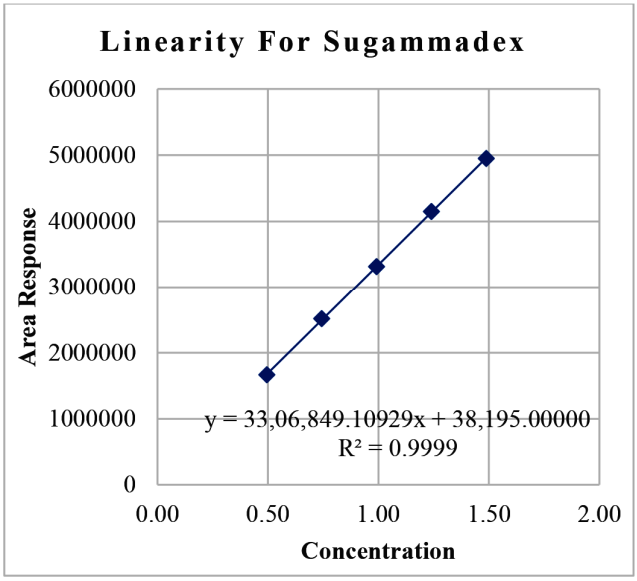


Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 053	4947956	100.000	1.17	5241

Chromatogram No 18-Linearity at 150% level-2

Table 10: Area Response of Linearity Solutions

S. No	Name	Linearity Level-50%	Linearity Level-75%	Linearity Level-100%	Linearity Level-125%	Linearity Level-150%
1	INJ-1	1651985	2493691	3315024	4145138	4939117
2	INJ-2	1667668	2524417	3317467	4146295	4947956

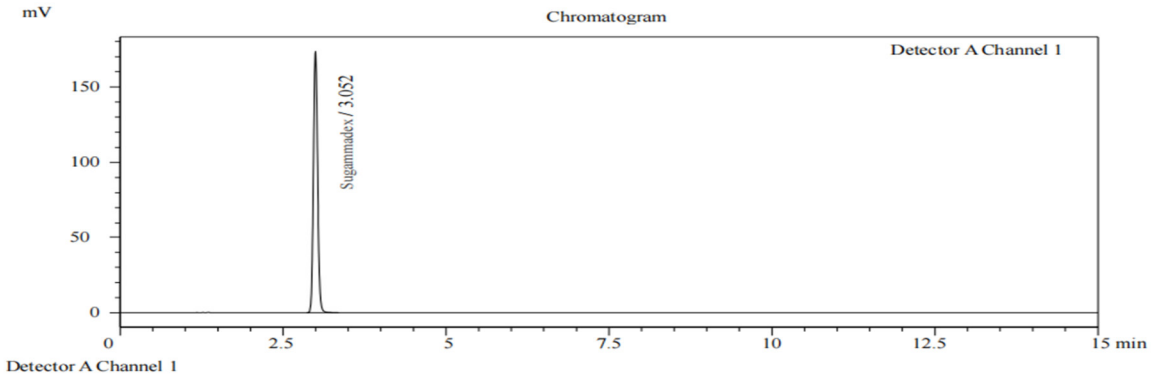


Slope	3306849.10929
Intercept	38195.0000
% Intercept	1.15
Correlation Co-efficient	0.9999
Regression Correlation Co-efficient(r^2)	0.9999

Chart 1: Area response vs Concentration

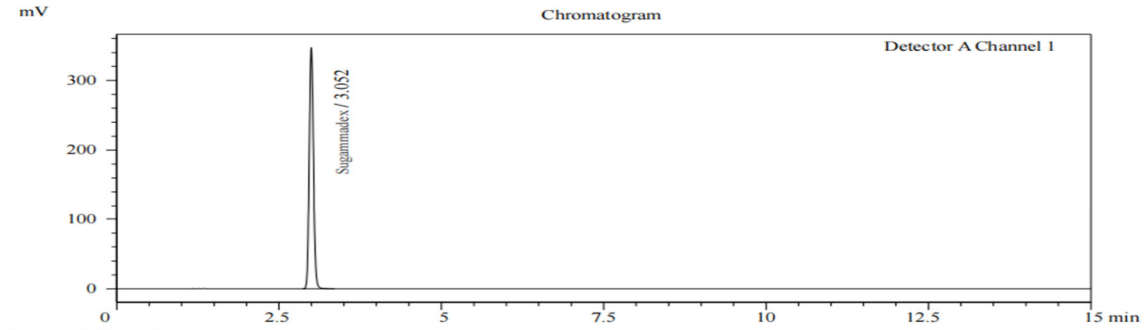
S.No	Acceptance Criteria	Result
1	Correlation Coefficient and Regression Coefficient should be NLT 0.998.	0.9999
2	% Y intercept should be ±2% at 100% concentration level.	1.15%

Accuracy



Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 052	1648389	100.000	1.17	5251

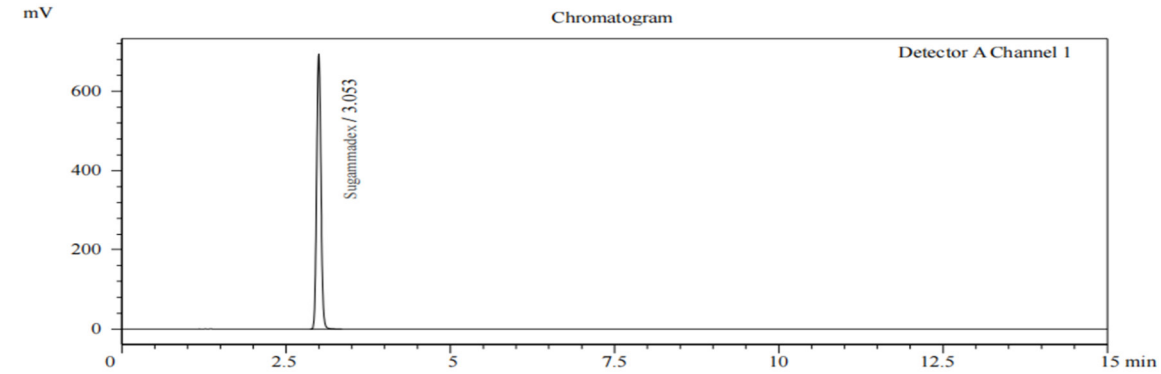
Chromatogram No 19 –Accuracy at 50% level



Detector A Channel 1

Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 052	3317777	100.000	1.17	5238

Chromatogram No 20 –Accuracy at 100% level



Detector A Channel 1

Name	RT	Area	Area %	Tailing Factor	Number of Theoretical Plates (NTP)
Sugammadex	3. 053	4947978	100.000	1.17	5241

Chromatogram No 21 –Accuracy at 150% level

Table 11: Area Response of Accuracy Solutions

S.No	NAME	ACCURACY LEVEL-50%	ACCURACY LEVEL-100%	ACCURACY LEVEL-150%
1	INJ-1	1648389	3317777	4947978
2	INJ-2	1644448	3317749	4947946
3	INJ-3	1644667	3317732	4947955

Table 12: Acceptance criteria of accuracy

S.No	ACCEPTANCE CRITERIA	% RECOVERY	RESULT
1	Accuracy level 50% (80-120%)	%Recovery	99.57
2	Accuracy level 100% (80-120%)	%Recovery	99.68
3	Accuracy level 150% (80-120%)	%Recovery	99.75

Test result of the Accuracy of 50%, 100% and 150% are complies within the limits.

Conclusion

A simple, rapid, specific and economic chromatographic method has been optimized for the assay of Sugammadex by RP-HPLC. The RP-HPLC determination was achieved with the mobile phase mixture in the ratio of 30:70 (Buffer: Acetonitrile). The RP-HPLC separation was achieved with the column - Waters Symmetry, C18, 4.6x250mm, 5µm diameter. The response was recorded at the 254nm using UV detector without any interference and the runtime was 15mins.The Auto sampler temperature was maintained at 5°C.The injection volume was about 10µL at the flow rate of 1.0

mL/min. The method was developed with the reference of ICH guidelines for Analytical Method Validation Q2 (R2), USP 40< 1225> Validation of compendial Methods, and USP <1226> Verification of compendial Methods. The method was successfully applied for the determination of assay of Sugammadex Active Pharmaceutical ingredient.

This proposed method can be optimized and applied for the determination of assay of Sugammadex Active Pharmaceutical ingredient at less time and at low cost.

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