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APPLICATION OF ION-PAIR COMPLEXATION PROCESS FOR THE SPECTROPHOTOMETRIC QUANTIFICATION OF RASAGILINE MESYLATE IN PURE AND TABLET FORMS

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ABSTRACT. The present study aims to develop and validate simple, rapid, cost-effective, sensitive, and extractive spectrophotometric methods for the determination of rasagiline mesylate in pure form and pharmaceutical formulations. The developed methods are based on the formation of ion-pair complexes between rasagiline mesylate with three dyes, namely, bromocresol purple, methyl orange, and alizarin red S, in acidic buffer solutions. Different factors affecting the reaction between rasagiline mesylate and the dyes were studied and optimized. The formed complexes were extracted with methylene chloride and measured at 410, 425, and 430 nm using bromocresol purple, methyl orange, and alizarin red S, respectively. Beer's law was obeyed in the ranges 1.0-16, 1.0-12, and 1.0-20 μg mL^{-1} when utilizing bromocresol purple, methyl orange, and alizarin red S, respectively, with a correlation coefficient ($r^2 \geq 0.9992$) under the optimum conditions. The limits of detection were 0.29, 0.30, and 0.29 μg $mL^{-1,}$ and the limits of quantification were 0.97, 1.0, and 0.93 μg mL^{-1} for bromocresol purple, methyl orange, and alizarin red S, respectively. Other method validation parameters have been evaluated. No significant statistical differences between the results of the proposed and the reported methods were obtained by applying Student's t- and F-tests.

KEY WORDS: Dosage forms, Dyes, Ion-pair complexes, Rasagiline mesylate, Spectrophotometry

INTRODUCTION

Rasagiline mesylate (RSG) is chemically designated as (1R)-2,3-dihydro-N-2-propynyl-1H-inden-1-amine. Rasagiline is a powerful, selective, and irreversible second-generation monoamine oxidase inhibitor that specifically targets the type B enzyme (MAO-B). The advantageous effects seen in models of dopaminergic motor dysfunction treated with rasagiline are largely attributable to elevated dopamine levels and improved dopaminergic activity. 1-Aminoindane is a powerful main metabolite that does not function as an MAO-B inhibitor. Rasagiline is utilized for the treatment of idiopathic Parkinson's disease, either as monotherapy or in conjunction with levodopa for patients suffering changes in dosage efficacy [1, 2].

The literature review revealed numerous analytical techniques employed for the detection of RSG in pharmaceuticals and biological fluids, including chromatography [3-9], electrochemistry [10], and spectrophotometry [11-18]. To our knowledge, there is no official monograph for rasagiline in any pharmacopoeia. The approaches are complex, requiring thorough and laborious preparation of samples and careful cleanup procedures prior to analysis.

UV-Vis molecular absorption is the foundation of the majority of ion-pair spectrophotometric assay techniques reported in the pharmaceutical industry. These techniques are sensitive, accurate, precise, resilient, and simple to use [20, 21]. In this area, one can find pharmaceutical compounds without a distinctive visible spectrum when combined with an organic dye. The extractive

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spectrophotometric procedures are widely utilized; they include extracting the ion pairs in an organic solvent and then further analyzing the extract. The ideal pH level, reagent concentration, and ionic strength must be determined for the quantitative extraction in the chosen organic solvent. An ion pair is formed through the electrostatic attraction between a positively protonated drug and a negative reagent [22-27].

The present investigation aims to develop simple, sensitive, and cost-effective methods for the determination of RSG in pure form and pharmaceutical formulations using the spectrophotometric technique. The methods are based on the formation of ion-associate complexes between RSG and the dyes bromocresol purple (BCP), methyl orange (MO), and alizarin red S (ARS) in an acidic buffer, which is extractable into methylene chloride. The proposed approaches have been statistically validated for accuracy, precision, sensitivity, selectivity, robustness, and ruggedness according to ICH recommendations [28].

EXPERIMENTAL

Instrumentation

The absorption spectra were obtained using a Shimadzu UV-1601 UV/visible double beam spectrophotometer from Sweden, which was equipped with a 10 mm quartz cell for measuring absorbance. The spectrophotometer offers a wavelength accuracy of ± 0.2 nm, a scanning speed of 200 nm/min, and a bandwidth of 2.0 nm within the wavelength range of 200-900 nm. The pH values of different buffer solutions were checked using a Hanna pH-meter instrument (pH 211) (Romania) equipped with a combined glass-calomel electrode.

Materials and reagents

All chemicals, solvents, and reagents utilized in this study were of analytical reagent or pharmaceutical quality, and all solutions were freshly produced on a regular basis. A pure sample of RSG with a purity of 99.60 ± 1.0% was provided by Al Rowad Pharmaceutical Industrial Co., Cairo, Egypt. Rasanopark tablets contain 1 mg of RSG per tablet and are produced by Al Rowad Pharmaceutical Industrial Co., Cairo, Egypt. Parkintreat tablets contain 1 mg of RSG per tablet and are produced by Sedico/Inspire Pharmaceutical Company, Cairo, Egypt.

Bromocresol purple (BCP), methyl orange (MO), and alizarine red S (ARS) (BDH Chemicals LTD, Poole, England) were used without further purification. Chloroform, methylene chloride, and carbon tetrachloride were obtained from BDH Chemicals Ltd. (Poole, England), and anhydrous sodium sulfate was obtained from Prolabo.

Preparation of standard solutions

Stock standard solutions (100 μg mL^{-1}) and (1.0×10^{-3} mol L^{-1}) of RSG were prepared by dissolving 10 and 26.73 mg of pure RSG, respectively, in the least amount of methanol and further diluted with bidistilled water to the mark in a 100 mL volumetric flask. The standard solutions were stable for at least 7.0 days when kept in the refrigerator. Serial dilution with the same solvent was performed to obtain the appropriate concentration range.

Stock solutions of BCP, MO, and ARS reagents 0.1% w/v and 1.0×10^{-3} mol L^{-1} were generated by dissolving 0.1 g and 0.054, 0.033, and 0.034 g of pure solid reagent in 10 mL of 96% ethanol and diluting to 100 mL with bidistilled water in 100 ml a volumetric flask. The solutions remained stable for a minimum of one week when stored in the refrigerator.

A series of buffer solutions of KCl–HCl (pH = 1.5-4.2), NaOAc–HCl (pH = 1.99-4.92), NaOAc–AcOH (pH = 3.0-5.6), and potassium hydrogen phthalate–HCl (pH = 2.0-7.0) were prepared by following the standard methods [29].

General procedures

Precisely measured aliquots (0.1-2.0 mL) of standard RSG solution (100 μg mL^{-1}) were put into 10 mL volumetric flasks. 3.0 mL of NaOAc–AcOH buffer at optimal pH levels of 3.0, 3.5, and 4.0 were administered using BCP, MO, and ARS, respectively. Subsequently, 2.0 mL of each reagent (0.1%, w/v) was included, and the total volume was adjusted to 10 mL using bidistilled water. The ion association complexes were extracted using 10 mL of methylene chloride. The solution was agitated for 2.0 minutes and then permitted to stand for the distinct separation of the two phases, after which the methylene chloride layer was filtered through anhydrous sodium sulfate. The absorbance of the yellow ion-pair complexes was quantified at 410, 425, and 430 nm utilizing BCP, MO, and ARS, respectively, against appropriately produced reagent blanks. All measurements were conducted at ambient temperatures. In the three proposed methodologies, a standard curve was established by graphing absorbance values against concentrations of RSG to determine the quantity of medication in unknown analyte samples.

Applications to pharmaceutical formulations

Twenty tablets containing RSG were meticulously ground and weighed. A measured amount of powdered tablets corresponding to 10 mg of RSG was placed into a 100 mL volumetric flask, about 20 mL of bidistilled water was added, and the flask was subjected to sonication for 30 minutes. We adjusted the volume using bidistilled water, mixed it thoroughly, and filtered through Whatman No. 1 filter paper into a 100 mL volumetric flask, discarding the initial 10 mL. Subsequently, the conical flask was rinsed with bidistilled water. The wash was included in the same volumetric flask, which was subsequently filled to the designated volume with bidistilled water. Aliquots with RSG at the specified final concentration ranges were examined according to the "General recommended procedure." The concentration of RSG was determined either by the calibration curve or by employing the relevant regression equation. The conventional addition method was employed for the precise quantification of RSG content.

Stoichiometric relationship

The stoichiometric ratios of the ion-associates produced between the investigated medications and the reagents were established using the continuous variation [30] and molar ratio [31] methods at the wavelengths of maximum absorbance. In the continuous variation approach, equimolar solutions were utilized: a 1.0 x 10^{-3} mol L^{-1} standard solution of RSG and a 1.0 x 10^{-3} mol L^{-1} solution of dye were employed. A series of solutions was produced in which the total volume of the examined medications and the dye was maintained at 2.0 mL. The drug and reagent were combined in diverse complementary ratios (0:2, 0.2:1.8, 0.4:1.6, …, 2:0, inclusive) and brought to volume in a 10 mL calibrated flask with the suitable solvent for extraction, adhering to the aforementioned protocol. In the molar ratio approach, the concentration of RSG is maintained at 1.0 mL of (1.0 x 10^{-3} mol L^{-1}), while the concentration of dye (1.0 x 10^{-3} mol L^{-1}) is systematically varied between 0.2 and 2.4 mL. The absorbance of the produced solutions was assessed at the optimal wavelength for each complex.

RESULTS AND DISCUSSION

Absorption spectra

The suggested approaches rely on the reactivity of the secondary amine group of RSG with dyes (BCP, MO, and ARS). RSG generates an ion-association complex with acid dyes that may be extracted as dichloromethane from the aqueous phase. The protonated nitrogen of RSG is

anticipated to attract the negatively charged components of sulphonphthalein anionic dyes in an acidic buffer solution at pH ≥ 3.0, functioning as a cohesive unit due to electrostatic attraction within the pH range of 2.5-5.0. This interaction results in the formation of a yellow ion-pair complex that can be extracted with an organic solvent. The absorbance spectra of the ion-pair complexes produced between RSG and reagents were recorded in the region of 350–550 nm relative to the blank solution. The ion-pair complexes of RSG with BCP, MO, and ARS exhibit peak absorbances at 410, 425, and 430 nm, respectively (Figure 1).

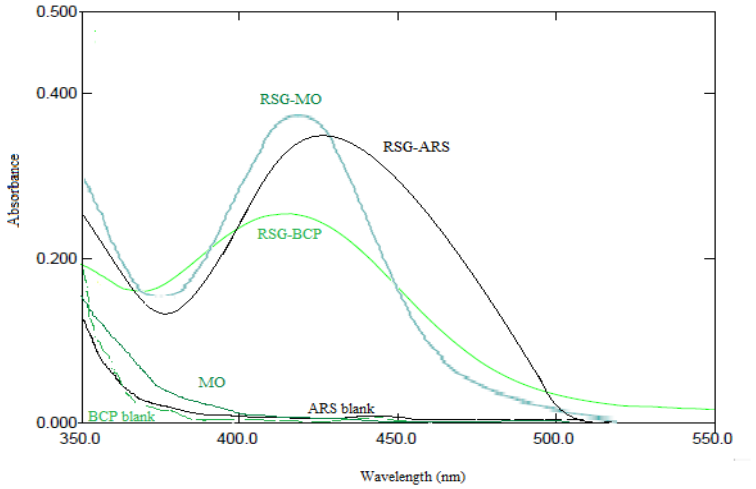


Figure 1. Absorption spectra of ion-pair complexes of 16, 12, and 20 μg mL^{-1} RSG using (0.1 %, w/v) BCP, MO, and ARS reagents, respectively, against reagent blank.

Optimum reaction conditions for complex formation

The procedures were meticulously optimized to attain complete reaction production, optimal sensitivity, and maximal absorbance. The reaction conditions for the ion-pair complex were determined through preliminary studies that examined factors such as buffer pH, organic solvent type, dye quantities, reaction duration, and temperature for the extraction of ion-pair complexes.

Effects of pH

The successful extraction of the complex is contingent upon the type of buffer employed and its pH value. The influence of pH was examined by isolating the colored complexes using several buffers, including NaOAc–HCl (pH = 2.0-4.5), NaOAc–AcOH (pH = 2.8-5.5), and potassium hydrogen phthalate–HCl (pH = 3.0-6.0). The highest color intensity and absorbance were observed in the NaOAc-AcOH buffer. The maximal absorbances of the ion pair complexes between RSG and the reagents were observed at pH 3.0, 3.5, and 4.0 utilizing BCP, MO, and ARS techniques, respectively (Figure 2(a)). The buffer volume was ascertained by conducting the same experiment while systematically varying the volume from 0.5 to 5.0 mL. A greater absorbance value and consistent results were achieved using 3.0 mL of the acetate buffer solutions.

Effect of extracting solvents

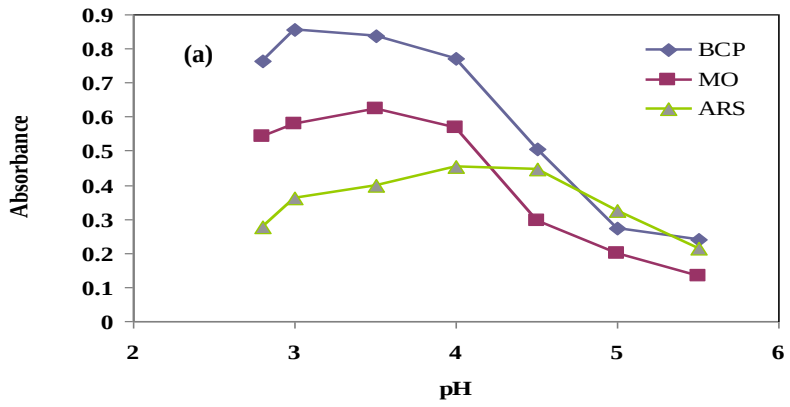
The impact of various organic solvents, including chloroform, carbon tetrachloride, methanol, ethanol, acetonitrile, n-butanol, benzene, acetone, ethyl acetate, diethyl ether, toluene, dichloromethane, and chlorobenzene, was examined for the efficient extraction of colorful species from the aqueous phase. Dichloromethane was identified as the best appropriate solvent for the quantitative extraction of colored ion pair complexes utilizing the examined reagents (Figure 2(b)). Experimental results demonstrated that twofold extraction with a total volume of 10 mL provided the optimal solvent, giving the highest absorbance intensity, steady absorbance for RSG, significantly lower extraction capability for the reagent blank, and the quickest time to achieve equilibrium between both phases.

Effect of reagent concentration

The impact of the reagents was analyzed by quantifying the absorbances of solutions with a constant concentration of RSG and varying volumes of the corresponding reagents (0.1%, w/v) within the range of 0.5 to 4.0 mL. The results indicated that the absorbance of the extracted ion-pair rose with the reagent amount up to 2.0 mL. The optimal color intensity of the complex was attained with 2.0 mL of each reagent solution at a concentration of 0.1% (w/v). A greater amount of the reagent did not significantly affect the absorbance of the resulting ion-pair complexes (Figure 2(c)).

Effect of shaking time and temperature

The optimal reaction time was examined from 0.5 to 5.0 minutes by monitoring the color development at ambient temperature (25 ± 2 °C). The maximum and consistent absorbance values were achieved after 2.0 minutes of shaking for all combinations (Figure 2(d)). Consequently, a shaking duration of 2.0 minutes was upheld for the entirety of the experiment. The influence of temperature on colored complexes was examined by assessing the absorbance values within the temperature range of 20-35 °C. The absorbance of the colored ion pair complex remained consistent up to 30 °C. At elevated temperatures, the concentration of the medication was shown to rise owing to the volatile characteristics of dichloromethane. Consequently, room temperature (25 ± 2 °C) was selected as the optimal temperature for the analysis of the investigated medicines in bulk and pharmaceutical formulations. The absorbance of the complexes remains constant for a minimum of 10 hours at ambient temperature.



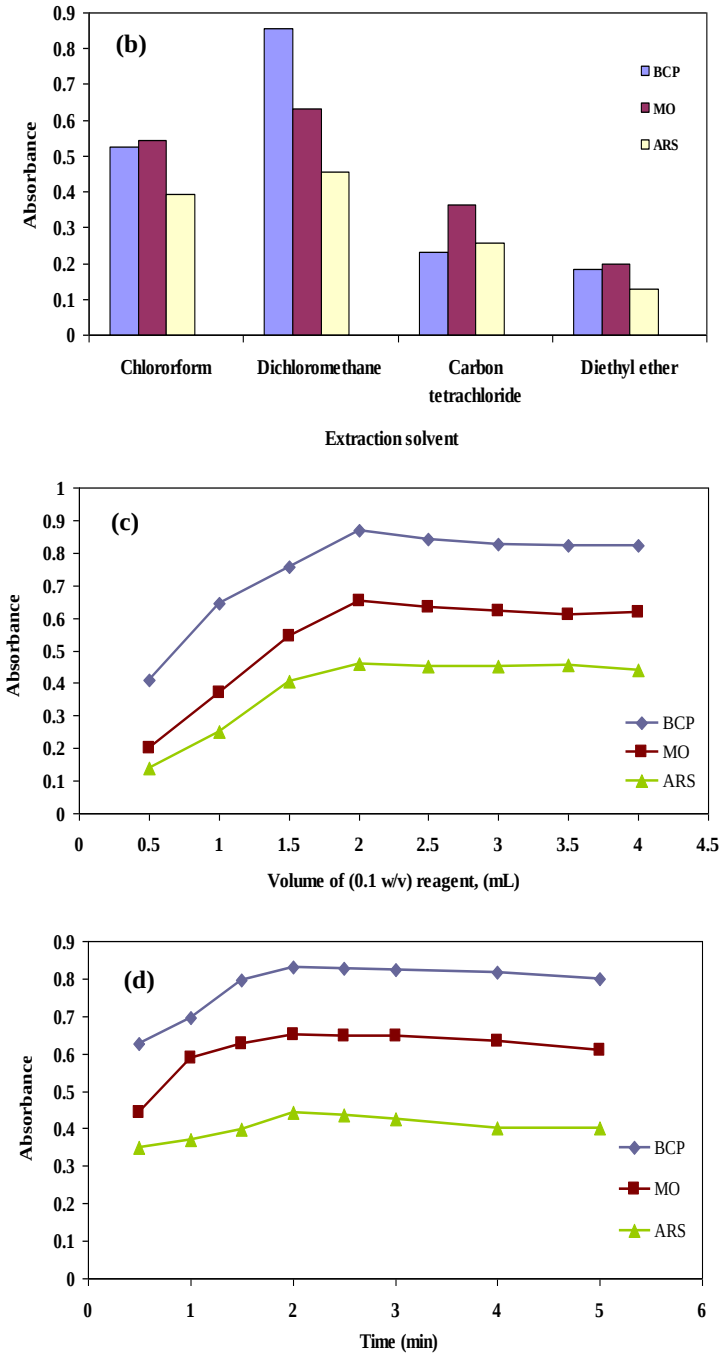


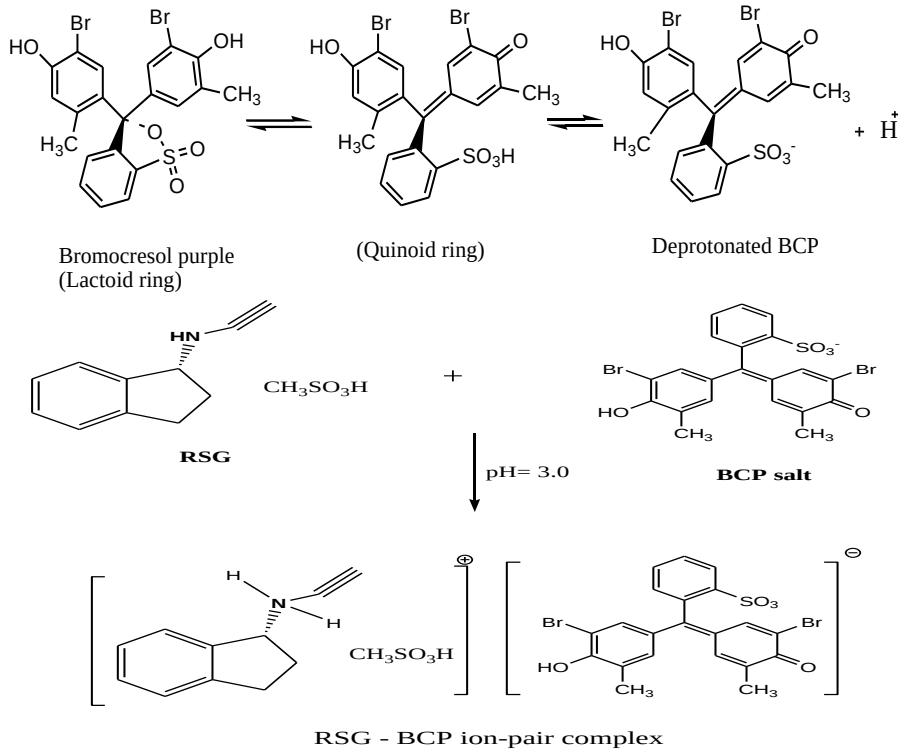
Figure 2. Effect of (a) pH of buffer solution; (b) extraction solvent; (c) volume of (0.1%, w/v) reagent and (d) time on the ion pair complex formation between (16, 12 and 20 μg mL^{-1}) RSG and (0.1%, w/v) BCP, MO and ARS reagents, respectively, (n = 3.0).

Stoichiometric ratio

The molar ratio of the reagents (RSG: dye) in the ion-pair complexes was determined by the continuous variations (Job's method) (Figure 3(a)) and the molar ratio method (Figure 3(b)). The results indicate that 1:1 for (RSG: dye) ion-pairs are formed through the electrostatic attraction between positive protonated RSG^+ and negative BCP^-, MO^-, or ARS^-. The extraction equilibrium can be represented as follows:

$$RSG^+_{(aq)} + D^-_{(aq)} \longleftrightarrow RSG^+ D^-_{(aq)} \longleftrightarrow RSG^+ D^-_{(org)}$$

Where RSG^+ and D^- represent the protonated RSG and the anion of the dye, respectively, and the subcript (aq) and (org) refer to the aqueous and organic phases, respectively (Scheme 1).



Scheme 1. Proposed reaction mechanism for the ion pair complex formation between RSG and BCP.

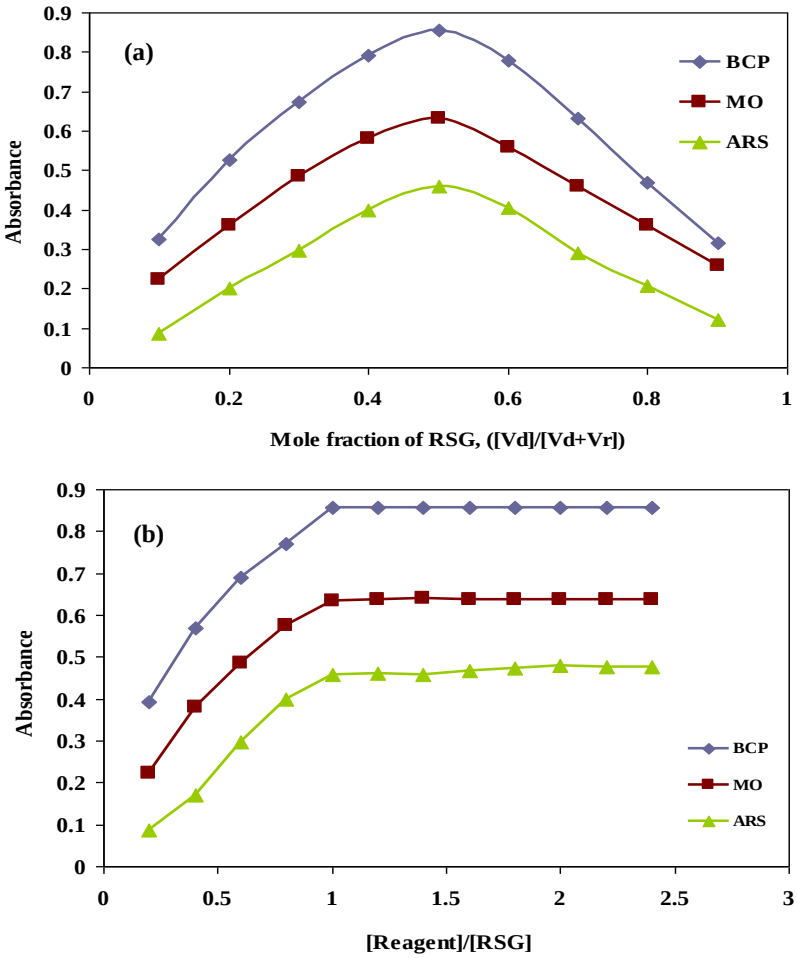


Figure 3. (a) Job's method of continuous variation graph and (b) mole ratio plot for the ion-association complexes of RSG (1.0 x 10^{-4} mol L^{-1}) with reagent solution (1.0 x 10^{-4} mol L^{-1}) at the optimum conditions.

Method of validation

The proposed method was validated according to ICH guidelines [28] concerning linearity, sensitivity, accuracy, precision, limit of detection (LOD), limit of quantitation (LOQ), robustness, and ruggedness.

Linearity and sensitivity

The absorbance-concentration relationship for the RSG medicine exhibited linearity throughout the concentration ranges of 1.0-16, 1.0-12, and 1.0-20 µg mL^{-1} when utilizing BCP, MO, and ARS, respectively, under the designated experimental conditions. The calibration graph is represented by the equation (A = a + b C), where A denotes absorbance, a signifies the intercept, b indicates the slope, and C represents concentration in µg mL^{-1}. This equation is formulated with

the least squares method. Table 1 presents the correlation coefficient, intercept, and slope for the calibration data. The molar absorptivity of the colored ion-pair complexes and the relative standard deviation were calculated and presented in Table 1.

ICH guideline [28] outlines various methods for establishing the limits of detection (LOD) and quantitation (LOQ). These factors consist of visual assessment, signal-to-noise ratio, and the utilization of the standard deviation of the response and the gradient of the calibration curve. The Limit of Detection (LOD) and Limit of Quantification (LOQ) of the method were established by injecting increasingly lower amounts of reference solutions using the devised technique. The Limit of Detection (LOD) and Limit of Quantification (LOQ) for the suggested approaches were determined using a specific equation [28, 32]:

$$LOD = 3s / k \text{ and } LOQ = 10\ s / k$$

where s is the standard deviation of ten replicate determinations of the reagent blank or the standard deviation of intercepts of regression lines, and k is the sensitivity, namely the slope of the calibration graph. In accordance with the formula, LODs were found to be 0.29, 0.30, and 0.28 μg mL^{-1}, and LOQs were found to be 0.97, 1.0 and 0.93 μg mL^{-1} using BCP, MO and ARS, respectively.

Table 1. Statistical analysis and analytical data in the determination of RSG using the proposed methods.

Parameters	BCP	MO	ARS
Wavelengths λ_{max} (nm)	410	425	430
Beer's law limits (μg mL^{-1})	1.0-16	1.0-12	1.0-20
Molar absorptivity ε, (l mol^{-1} cm^{-1}) x 10^4	1.1864	1.3217	0.6546
Sandell's sensitivity (ng cm^{-2})	22.53	20.23	40.08
Regression equation [a]			
Intercept (a)	0.011	-0.0009	0.0031
Standard deviation of intercept (S_a)	0.039	0.007	0.028
Slope (b)	0.0495	0.0503	0.0229
Standard deviation of slope (S_b)	0.015	0.018	0.016
Correlation coefficient (r)	0.9994	0.9992	0.9996
LOD (μg mL^{-1})	0.29	0.30	0.28
LOQ (μg mL^{-1})	0.97	1.0	0.93
Mean ± RSD%[b]	99.40 ± 1.05	99.90 ± 0.80	100.20 ±0.70
Relative error, RE% [b]	1.10	0.84	0.74
Variance	1.10	0.64	0.49
t-test [c]	0.32	0.56	0.98
F- test [c]	1.36	1.27	1.65

[a]A = a + bC, where C is the concentration in μg mL^{-1}, A is the absorbance units, a is the intercept, b is the slope, [b]RSD%, percentage relative standard deviation; RE%, percentage relative error, [c]The theoretical values of t and F at P = 0.05 are 2.571and 5.05, respectively, at confidence limit at 95% confidence level and five degrees of freedom (p = 0.05).

Accuracy and precision

The accuracy of the proposed approach was evaluated by examining three different concentrations of RSG within the linearity range across six replicates. Accuracy was measured using recovery percentage and percent relative error (RE%) for RSG, whilst precision was evaluated by relative standard deviation (RSD%). Intra-day precision was assessed on a single day, whereas inter-day precision was evaluated on three distinct days (n = 6 for each level). The results of this investigation are presented in Table 2. The minimal values of the relative standard deviation (RSD%) and percentage relative error (RE%) indicate a high degree of precision and accuracy in the proposed methodologies.

Table 2. Intra-day and Inter-day accuracy and precision data for RSG obtained by the proposed methods.

Method	Added concentration (μg mL^{-1})	Intra-day			
		Recovery %	Precision RSD % [a]	Accuracy RE %	Confidence limit [b]
BCP	5.0	99.30	0.53	-0.70	4.996 ± 0.026
	10	99.50	0.65	-0.50	9.950 ± 0.065
	15	99.10	0.82	-0.90	14.865 ± 0.122
MO	4.0	100.60	0.47	0.60	4.024 ± 0.019
	8.0	99.20	0.72	-0.80	7.936 ± 0.057
	12	100.20	1.17	0.20	12.024 ± 0.141
ARS	5.0	100.10	0.49	0.10	5.005 ± 0.025
	10	99.80	0.79	-0.20	9.98 ± 0.079
	15	99.70	1.01	-0.30	14.955 ± 0.151
		Inter-day			
BCP	5.0	100.60	0.43	0.60	5.03 ± 0.022
	10	99.30	0.59	-0.70	9.930 ± 0.059
	15	99.90	0.83	-0.10	14.985 ± 0.124
MO	4.0	99.30	0.51	-0.70	3.988 ± 0.02
	8.0	99.70	0.70	-0.30	7.976 ± 0.056
	12	100.30	1.10	0.30	12.036 ± 0.132
ARS	5.0	99.60	0.62	-0.40	4.98 ± 0.031
	10	99.40	0.87	-0.60	9.94 ± 0.086
	15	100.20	1.24	0.20	15.03 ± 0.23

[a]Mean ± standard error (n = 6), RSD%, percentage relative standard deviation; RE%, percentage relative error, [b]Confidence limit at 95% confidence level and five degrees of freedom (t = 2.571).

Robustness and ruggedness

The method's robustness was assessed by implementing minor incremental alterations in dye volume, pH, and shaking duration, and the impact of these modifications on the absorbance of the colored systems was analyzed. The alterations exerted minimal impact on the outcomes, as indicated by the low intermediate accuracy values represented as RSD (≤ 3.0 %). The robustness of the method was evidenced by analyses conducted by two independent analysts, as well as by a single analyst utilizing two distinct instruments inside the same laboratory. The results indicated no statistical discrepancies among various analysts and equipment, implying that the suggested approaches were both robust and resilient. The intermediate precision values (RSD%) in this study were < 3.0%, signifying adequate ruggedness (Table 3).

Table 3. Method robustness and ruggedness are expressed as intermediate precision (RSD %) for the ion pair formation of RSG with the studied reagents.

Methods	Nominal concentration (μg mL^{-1})	RSD%			
		Robustness		Ruggedness	
		Variable alerted [a]			
		pH[b]	Volume of Dye[c]	Inter-analysts	Inter-instruments
BCP	5.0	0.56	1.05	0.84	1.10
	10	0.81	1.40	1.23	1.60
	15	1.30	1.90	1.50	2.07
MO	4.0	0.80	1.0	0.75	1.10
	8.0	0.70	1.42	1.30	1.70
	12	1.70	1.90	2.50	2.10
ARS	5.0	1.20	1.50	0.55	2.30

	10	1.0	1.80	1.40	1.80
	15	1.86	2.14	1.60	1.20

[a]Mean of three determinations, [b]pH (±0.2), [c]The volumes of reagent used were 2.0 ± 0.2 mL.

Effects of interference

The study evaluated the impact of diluents, excipients, and additives often associated with RSG in its dosage forms, including starch, lactose, glucose, sucrose, talc, sodium chloride, titanium dioxide, and magnesium stearate, to determine the method's efficacy. The results demonstrated the absence of interference from excipients and additives, signifying a good selectivity for quantifying RSG in its dosage forms.

Analysis of pharmaceutical formulations

The proposed approaches have been effectively utilized for the determination of RSG in pharmaceutical dosage forms. The proposed methodologies were effectively utilized for the quantification of RSG in pharmaceutical formulations. Six repeat measurements were conducted. Furthermore, to verify the efficacy of the proposed procedures, dose forms were evaluated for potential interaction with the usual addition method (Table 4). No substantial variation was observed between the slopes of the calibration curves and the standard addition procedures across the four techniques. Consequently, it is determined that the excipients in the pharmaceutical dosage forms of RSG did not interfere with the analysis of RSG. The results were contrasted with those acquired by the approved or documented procedure for RSG [16]. The statistical analysis of the results revealed no significant difference in accuracy and precision between the suggested methods and the reported methods in pharmaceutical formulations, as indicated by the Student's t-value and variance ratio F-value at a 95% confidence level [32]. The findings indicate that the student's t- and F-values at a 95% confidence level did not surpass the theoretical values, so confirming a strong concordance between the results derived from the suggested approaches and the established method in terms of accuracy and precision (Table 5).

Table 4. Application of the standard addition method for the determination of RSG in dosage forms (tablets) using the proposed methods.

Method	Taken drug ($\mu g\ mL^{-1}$)	Pure drug added ($\mu g\ mL^{-1}$)	Dopaminic tablets (1.0 mg)		Parkintreat tablets (1.0 mg)	
			Total found ($\mu g\ mL^{-1}$)	Recovery [a] (%) ± SD	Total found ($\mu g\ mL^{-1}$)	Recovery [a] (%) ± SD
BCP	6.0	3.0	8.928	99.20 ± 0.43	8.991	99.90 ± 0.58
		6.0	12.048	100.40 ± 0.80	11.880	99.00 ± 0.76
		9.0	14.910	99.40 ± 0.74	15.045	100.30 ± 0.90
MO	4.0	2.0	6.012	100.20 ± 0.90	6.030	100.50 ± 0.80
		4.0	7.968	99.60 ± 1.10	7.912	98.90 ± 1.30
		6.0	9.900	99.00 ± 0.60	9.930	99.30 ± 0.50
ARS	6.0	3.0	9.045	100.50 ± 0.55	8.928	99.20 ± 1.50
		6.0	11.952	99.60 ± 0.87	12.073	100.60 ± 0.80
		9.0	14.895	99.30 ± 0.40	14.850	99.00 ± 1.30

[a]Average of six determinations.

Table 5. Results of analysis of tablets by the proposed methods for the determination of RSG and statistical comparison with the reported method.

Samples	Recovery [a] (%) ± SD			
	Proposed methods			Reported Methods [16]
	BCP	MO	ARS	
Dopaminct tablets (1.0 mg)	99.67 ± 0.64	99.50 ± 0.60	99.80 ± 0.62	99.60 ± 0.80
t-value [b]	0.15	0.22	0.44	
F-value [b]	1.56	1.78	1.66	
Parkintreat tablets (1.0 mg)	99.73 ± 0.66	99.57 ± 0.83	99.60 ± 0.87	100.10 ± 0.86
t-value [b]	0.76	0.99	0.91	
F-value [b]	1.70	1.07	1.02	

[a]Average of six determinations, [b]The theoretical values of t and F are 2.571 and 5.05, respectively at confidence limit at 95% confidence level and five degrees of freedom (p = 0.05).

CONCLUSION

This study details the utilization of extractive ion-pair complexation reactions with dyes for the detection of rasagiline mesylate (RSG) in both pure and prescription formulations. In comparison to the current spectrophotometric method, the proposed techniques are comparatively straightforward, swift, economical, and exhibit greater sensitivity for the quantification of RSG. Furthermore, the proposed approaches eliminate the cumbersome experimental procedures, such as heating, associated with the previously disclosed method. The primary advantage of these approaches is their relative immunity to interference from typical diluents and excipients present in quantities beyond their usual levels in pharmaceutical formulations. The statistical characteristics and recovery data indicate high accuracy and precision of the approaches. Consequently, the validated methodologies may prove advantageous for the routine quality control assessment of RSG in both raw materials and pharmaceutical formulations.

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