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Colorimetric Estimation for Salbutamol-sulphate in Pure Form and in Different Types of Pharmaceutical

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Abstract

A new sensitive, simple and accurate colorimetric approach is suggested of the estimation of salbutamol sulphate drug in pure form, also in different types of pharmaceutical. The approach is established on the conjunction of salbutamol (SLB) drug and the reagent 4-aminoantipyrine (4-AAP) reagent in basic medium to obtain a newly ligand that reacts with cobalt (II) to produce highly intensity red colour complex at 60°C. The water soluble dye is stable and estimated colorimetric ally with maximum absorption at 500 nm. The calibration curve between the concentration and the absorbance shows that the range of concentration was applied by the Beer's law between 2-60 µg/mL. The optimization of the experiential circumstances is examined. The precision and the accuracy for the approach are tested by the average relative standard deviation values (1.32%) and the average recovery values (100.23%) respectively. That it is based on the concentration. The approach sensitivity is obtained by molar absorptivity (0.6558×10^4 $l.cm^{-1}.mol^{-1}$). The sensitivity of Sandell is calculated (0.036 $\mu g.cm^{-2}$). The analytical data for the approach is matched with the standard method. The general interference from drug additives was examined. The suggested approach is successfully applied on the estimation of SLB in various types of pharmaceutical.

Keywords: Colorimetric; Estimation; Salbutamol sulphate; Pure form; Types of pharmaceutical

Introduction

Salbutamol sulphate (SLB), IUPAC name was bis[(1RS)-2-[(1,1-dimethylethyl) amino]-1-[4-hydroxy-3-(hydroxyl methyl) phenyl] ethanol] sulphate **(Figure 1)**, it is a 2-sympathicomimetic drug which was used as drug in the markets in 1973s [1]. It is too known as albuterol. SLB is utilized at first in the bronchial asthma treatment, it is applied as drug for the other types of the disease of allergic airways, and it is worked as a β2 adrenergic receptor agonist. So SLB is acted as its cardiovascular, and a bronchodilator influences are smaller than its bronchodilator actions drug is utilized in obstetrics forth on the premature labour prevention also as a nasal decongestant [2-4].

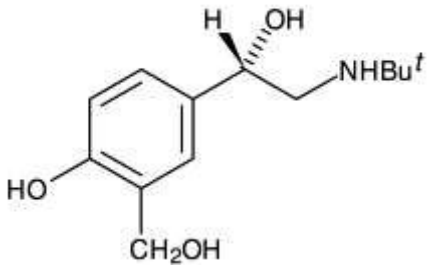

Figure 1 The chemical structure of salbutamol.

Soluble freely in water, very slightly soluble or practically insoluble in ethanol (96 %) also in the methylene chloride [5]. Different approaches have been utilized for the estimation of SLB, involving liquid chromatography-tandem mass spectrometry [6], high performance liquid chromatography [7-9], the gas chromatography conjugated with mass spectrometry [10] flow injection analysis [11], polarographic [12] derivative ultraviolet spectrophotometry [13], capillary electrophoresis [14] and the spectrophotometric (colorimetric) methods [15].

The colorimetric estimation procedures of (S such as charge-transfer complex formation [16], LB) in pharmaceuticals were dependent on the simple chromogenic diverse reactions diazotization coupling reaction [17], redox [18,19], reduction followed by chelation [20], oxidative coupling [21,22], nitrosation [23] and nitration [24].

The current investigation is aimed mainly for development A new sensitive, simple and accurate colorimetric approach for the estimation of salbutamol depended on the coupling between the drug with (4-AAP) to obtain a newly ligand that combined with cobalt (II) to produce highly intensity red colour complex at 60°C. The approach is applied in pure drug form and in different types of pharmaceutical with highly precision and accuracy.

Materials and Methods

Experimental apparatus

Every spectral measuring's were performed on double-beam UV-Visible 160 recording digital spectrometer (Japan) and using 1 cm silica cells, ice-water bath, sensitive balance ,pH meter, Jenway 3020.

Chemicals and reagents

All substances utilized were of analytical grade and it was received from BDH and Fluka companies, the pure drug salbutamol sample was supplied from SDI Company, Samara, Iraq. Dosage forms were received from commercial resources.

Sodium hydroxide solution (0.05 M) was made by dissolution (0.2 g) of (NaOH) in deionized water after that palliated to (100 mL) in the volumetric flask.

Cobalt chloride ($CoCl_2.5H_2O$) (0.1%) solution was made by dissolution (0.1 g) of cobalt salt with deionized water and palliated to 100 mL in the volumetric flask.

(4-AAP) 4-Aminoantipyrine (1%) made by dissolution (1 g) of (4-AAP) in little quantity of ethanol and palliated to the label in 100 mL calibrated flask with deionized water.

Salbutamol (standard solution) of (500 µg/mL) was made by dissolution 0.05 g of SLB pure in deionized water and palliated to the label in 100 mL calibrated flask with deionized water and putted in black container and leave in the refrigerator. This solution was utilized in the next experiments.

Procedure for pure drug

Standard volumes (0.1–3 ml) from (500 µg/mL) of pure SLB drug, were transmitted into a chain of 25 ml calibrated flasks, after that added 1 mL of 0.1% cobalt salt,1.5 mL of 1% 4-AAP, and 0.5 mL of 0.05 M NaOH. The mixture was putted in the water bath checked for 70 min at 60°C. The red complex was produced, achieved and cooled to 25 mL with deionized water, the absorbance values were computed at 500 nm versus the blank solution. The color for the dye formed is stable for the next day.

The working curve was built by utilizing the above approach utilizing standard drug solutions.

(0.5-3 mL) volumes=(2-60 µg/mL) concentration

Sample preparation procedure

Tablets samples: Finely powdered and weighed 20 tablets from kind of tablets (each tablet including 2 mg of salbutamol) [25]. A powder amount was equivalent to 0.05 gm from each SLB was accurately weighed and transmitted into a beaker (50 ml). The completely powder was dissolute in deionized water and the filtered solution was through a filter paper Whatmann. After that filtering to remove the non-dissolute ingredients it was transmitted in the (100 mL) volumetric flask and palliated to the final volume by the deionized water. A drug solution liquid was analyzed as examined in general approach.

Syrup sample: The contents of two bottles of SLB syrup (Butadin®syrup) [each 5 mL from syrup contains 5 mg SLB] were taken and mixed well, after that taken 125 mL from the syrup solution that was containing 0.05 gm from the SLB. The standard working solutions were made by appropriate palliation from this solution and the recommended approach was utilized for the estimation for albutamol.

Pressurized inhalation sample: Three canisters from pressurized inhalation sample of SLB (Vental inhaler) [each canister contains 0.02 mg SLB in 20 mL volume] were taken and mixed well, after that taken 60 mL from the sample that was including 0.05 gm from the SLB. The standard solution was prepared by suitable dilution from this solution that was analysed by the studied approach.

Result and Discussion

The optimization of the experiential circumstances influencing the reaction of salbutamol with 4-AAP and cobalt chloride was examined accurately **(Figure 2)**.

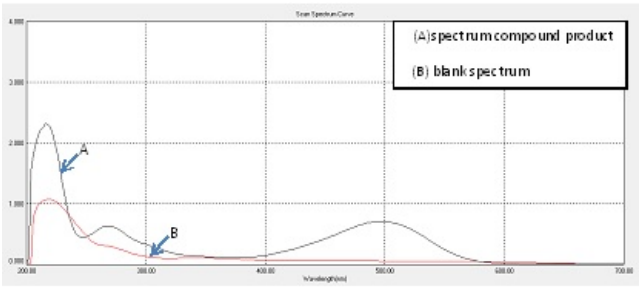

Figure 2 (A)Absorption spectra of (20 µg/mL) of (SLB) processing as studied by the approach and computed versus blank,(B) Absorption spectra of blank that was including (4-AAp), CoCl2 and NaOH in the final volume (25 mL).

Absorption spectrum

SLB reacts with 4-AAP to obtain a newly ligand in the existence of sodium hydroxide that reacts with cobalt II to produce strongly intensity red colour complex after the heating for 70 min at 60°C, as appeared in **Figure 2**, the spectrum of absorption of which under optimum circumstances gives a maximum at 500 nm.

Medium influence

The medium of medium on the absorbance of the product solution was examined; the basic medium was the best for the reaction. bases like ammonia, ammonium hydroxide, sodium hydroxide, potassium hydroxide and sodium carbonate were realized and given that sodium hydroxide highly sensitivity than other bases, that used in the examined approach, the influence of additional volumes for NaOH As appeared by **Figure 3**, it was showed that the highly absorbance for the chelating complex product gave at λ_{max} (500 nm) by utilizing 0.5 mL of 0.05 M NaOH. So that the pervious constant amount of sodium hydroxide was utilized in every next tests.

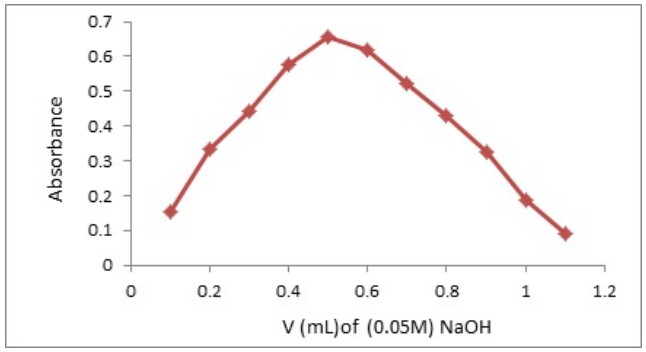

Figure 3 The influence of additional volumes for NaOH on the absorbance of the colouring product.

Influence of the quantity of 4-AAP

By using constant quantity of the drug solution ,the different concentrations of 4-AAP solution were utilized to the volume 1.5 mL from solution 1% was found sufficient to the colour increasing of the product to give highly intensity **(Figure 4)**, with a minimal value blank also was assumed to be prefect.

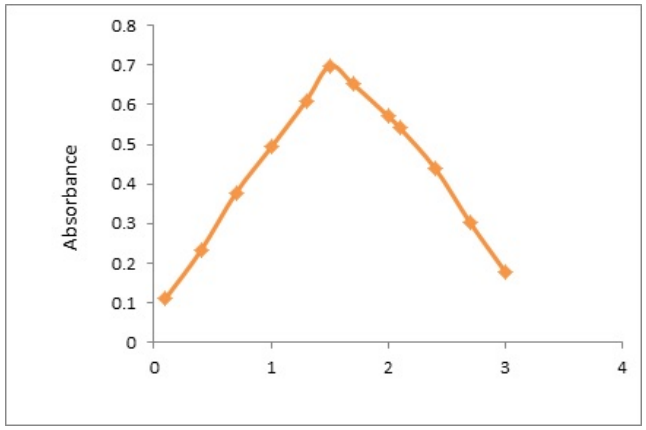

Figure 4 The influence of (4-AAP) concentration on the absorbance of the colouring product.

Influence of $CoCl_2.5H_2O$ concentration

The colouring complex product was given with highly absorbance when 1 mL of 0.1% concentration of $CoCl_2.5H_2O$ solution was utilized with a mixture of 4-AAP, salbutamol and sodium hydroxide **(Figure 5)**, so that, this quantity was utilized in the approach since it obtains highly sensitivity and minimal blank value.

Reaction time and temperature influence

The time of reaction was investigated by the showing of the colour improvement at temperature of room and at various temperatures in thermostatically controlled water-bath. The absorbance was computed at 5 min periods versus reagent of blank treated in the same method. As appeared in **Figure 6**, the figure was saw that production of the product complex for SLB was carried out ultimate at 60°C after 70 min and fixed for at least 3 hour.

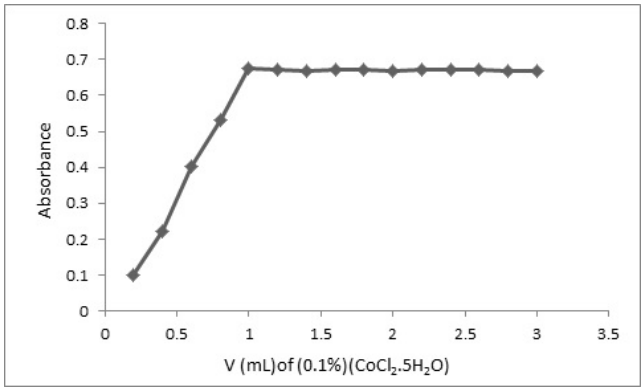

Figure 5 The influence of $CoCl_2.5H_2O$ concentration on the absorbance of the colouring product.

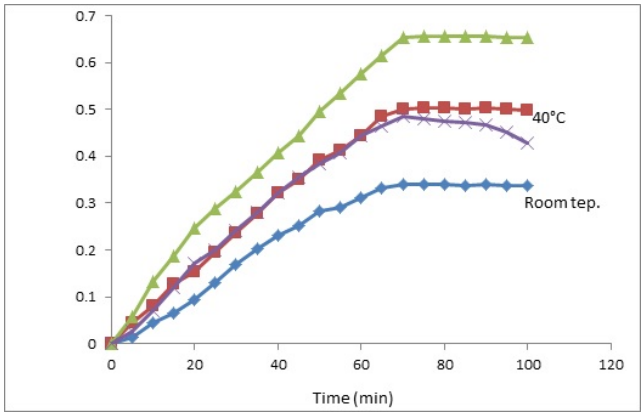

Figure 6 The influence of improving time and temperature on the absorbance of a colouring product.

Order of addition influence

To get the prefect results, the addition order of reagents must be pursued as obtaining by utilized the examined approach; moreover a decrease in the colour intensity was noted.

Quantification

So as to estimate the concentration range for the coloured product involve to the Beer's law, a computed absorbance of the product was at the value of λ_{max} (500 nm) after the color increasing by utilized the examined approach for the solutions sequence including increase quantities of SLB **(Figure 7)**. Sandell's sensitivity, molar absorptivity, and the Beer's law limits were estimated and showed in **Table 1**, it was appeared the sensitivity for the studied approach. The linear was computed from the corresponding correlation coefficient also the regression equation for SLB estimation into the studied approach appears premium linearity. The accuracy (average recovery %) and the precision (Relative Standard Deviation-RSD)

for the five replicates analysis of every three various concentrations for SLB (30, 15 and 5 µg/mL) showed that the approach is accurate additionally precise. LOQ and LOD are computed for the studied approach. Surely, the LOQ a little bit passes the minimum of the Beer's law range. However, LOD is as well as less the minimum of the Beer's law range [26].

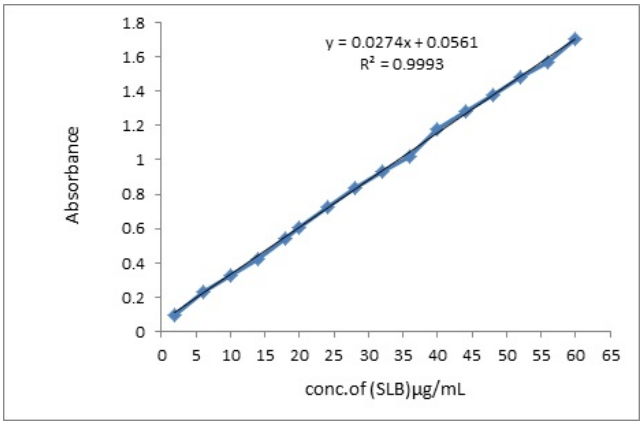

Figure 7 The calibration curve of SLB.

Table 1 Synopsis of visual properties also the analytical information for the examined approach.

Parameter	Values of approach
limits of Beer's law	(2.0-60.0) (µg/ml)
Correlation coefficient	0.9993
Sandell's sensitivity	0.036 (µg.cm^{-2})
Molar absorptivity	0.6558×104 (L.mol-1.cm^{-1})
Limit of quantitation	1.3412 (µg/ml)
Limit of detection	0.5510 (µg/ml)
Regression equation	(Y)*
Intercept	b 0.0561
Slope	a 0.0274
Average recovery	100.23%
RSD**	1.32%
*Y=a X+ b, where the concentration is X of (SLB) with (µg/mL)	
**Five Average for the estimations	

Interference

The interferences ambit by several excipients that predominatingly combined with the pharmaceutical dose forms were examined by computing the absorbance for the solutions including 20 µg/mL of SLB and every one of the excipients was taken separately in concentration (200 µg/mL). It was tested by utilizing the like approach in the calibration curve in the end volume of 25 mL. The results showed that the examined excipients do not influence in the estimation of salbutamol in its dosage forms (Average of three estimations) **(Table 2)**.

Table 2 Investigation of 20 ppm salbutamol SLB in the being of excipients.

Excipients	% Error	% Recovery
Acacia	+ 2.400	102.400
Talc	- 3.100	96.900
Glucose	+2.200	102.200
starch	- 2.200	97.800
lactose	+4.100	104.100
Vitamin C	-3.400	96.600
Sucrose	+.2.250	102.250
Glycerin	2.850-	97.150
magnesium stearate	- 4.100	95.900
PVP	- 1.550	98.850
Aspartate	+ 2.100	102.100
Sodium chloride	- 2.650	97.350

Structure of the product

It is obvious from the literatures [27-30] that a mole ratio and continuous variation method (Job's method) of phenolic compound: 4AAP was 1:1 formation a new ligands existence minimum absorbance. The absorbance sensitivity has been improved by its reaction with Co(II) to give the intensity of color for the resulting complex. By utilizing the continuous variation method (Job's method) and the method of molar ratio. The results obtained appeared that the colored complexes with stoichiometric ratio of 2:1 [4-AAP-phenolic drug] ligand:Co(II). The obvious stability constant for the resulting complex were computed by comparison the absorbance of solution that involving equivalent amounts of new ligand [4-AAP-phenolic drug] and Co(II) and other solution containing a five-fold excess of Co(II) ion from the starting concentration. The perfect amount for the utilizing solution was 1 mL of 2×10^{-3} M. The average conditional stability constants the resulting complex in water under the examined experiential circumstances is 5.34×10^{5}. The reaction may proceed as given in the following scheme **(Figure 8)**.

Analytical Applications

The studied approach was felicitously utilized to estimate SLB in its pharmaceutical dose forms. The results obtained were made statistical comparison by a variance ratio (F-test) for precision and a Student's t-test for accuracy with the standard approach [5] (basing on the titration for pure (SLB) potentiometric ally by utilizing perchloric acid (0.1 M) at the confidence level (95%) with five degrees of freedom, as seen in

Table 3. The results appeared that the F-test and t-test were below the theoretical value (F=6.39, t=2.31), pointing there was no clear distinction between the examined approach and standard approach (Average of three investigations) [31]. Furthermore, the studied approach is compared favourably with other reported approaches as appeared in **Table 4**.

Table 3 Estimation of (SLB) in pharmaceutical dose forms utilized the examined approach and comparing with the standard approach.

SLB pharmaceutical preparations	Examined approach		Standard approach		Nominal Values (t), (F)
	Recovery%	RSD%	Recovery%	RSD%	
Pure salbutamol	100.23	1.32	99.92	1.21	(F)Value=1.93 (t)Value=1.07
Butadin (tablets) (2 mg/Tab) S.D.I,Iraq	99.84	1.83	99.77	1.66	
Butadin tablets (2 mg/Tab) (Dijla), Iraq	100.44	1.65	99.89	1.04	
Butadin (syrup) (2 mg/5 ml) S.D.I, Iraq	100.04	1.21	99.93	1.21	
Ventral inhaler(SLB) (0.1/DOSE) (Arab drug company) Cairo, Egypt	100.14	1.51	99.88	1.47	

Table 4 Comparing of results for the estimation of SLB by the examined approach and the reminded approaches.

Reagent used	Λmax (nm)	Beer's law limit (µg.ml-1)	Molar absorptivity (L.mol-1cm-1)	Application	Remarks
Cerium(IV)– MBTHa [18]	530	0-15	2.4×10^{-4}	-	contains extraction and an expensive reagent
Ferricyanide 4-Aminophenazone [32]	505	25-175	-	-	Heating waiting, for 30 min
Diazotized 4-minoacetophenone [33]	463	0.5-30	2.72×10^{-4}	Tablet, syrup	-
Chloramine-T N,N-Dimethyl-pphenylenediamine [34]	620	Oct-40	-		Extraction with
Diazotized o-nitroaniline [35]	448	Feb-40	1.58×10^{4}	Tablet, syrup	
BrO3 —Br– /methyl orange [21]	510	0.5-5	7.17×10^{4}	Tablet	Includes some reagents and difficult conditions
F–C reagentb [16]	750	Jan-15	-------	Tablet, urine	Uses flow injection and extraction
sodium carbonate, hydroxyl ammonium [36]	701	100-500	6.24×10^{3}	Tablet, injection	-
diazotized 2,4-initroaniline [36]	558	02-Jun	9.33×10^{4}	Tablet, syrup	-
4-AAP-Co	500	Feb-60	0.6558×10^{4}	Tablet, syrup Ventral inhaler	Examined approach
aMBTH, 3-methylbenzothiazolin-2-one hydrozone					
b Folin–Ciocalteu reagent, F–C reagent					

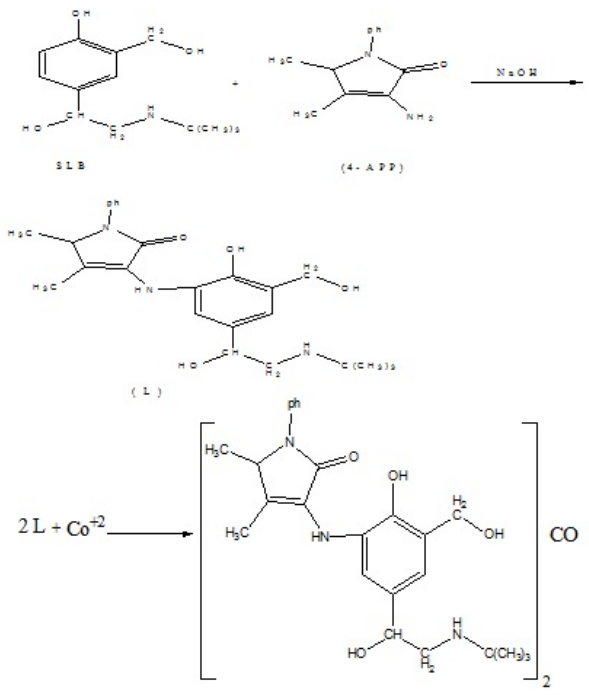

Figure 8 Scheme of possible reaction pathway for the complex formation of SLB drug with 4-APP and Co(II).

Conclusion

The studied approach is fairly sensitive, simple and economic when comparison with previously reported approaches specially those established on non-aqueous midst and costly technicality such as HPLC that do not need any treatment for the drug or the approach of extraction and give a perfect precision and accuracy. The approach is necessary for the estimation of pharmaceutical specimens of SLB (syrup and tablet), and the producing data founded there is no interference with the additive existent in common dose forms.

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