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Spectrophotometric Method for the Simultaneous Determination of Pseudoephedrine and Triprolidine in Bulk and Tablet Forms

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Abstract

A spectrophotometric method was developed for the simultaneous determination of pseudoephedrine HCl (PSE) and triprolidine HCl (TRI) in bulk and dosage forms. The method involved the determination of pseudoephedrine in the presence of triprolidine using two wavelengths (257 nm & 290 nm). Beer's law was obeyed in the concentration (152-760 µg/ml) and (6.4-32 µg/ml) with good linearity (0.9996 and 0.9996) for pseudoephedrine and triprolidine respectively. The accuracy and the precision of the developed method were very good (RSD < 2%). The validity of the proposed method was confirmed through the statistical comparison of the obtained data with those of the official USP method.

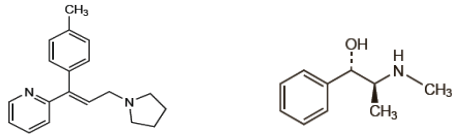
Keywords: Spectrophotometry, Simultaneous, Triprolidine, Pseudoephedrine.

1. Introduction

Pseudoephedrine (PSE) is a direct and indirect-acting sympathomimetic. It is a stereoisomer of ephedrine and has a similar action, but has been stated to have less pressor activity and fewer CNS effects. Pseudoephedrine and its salts are given orally for the symptomatic relief of nasal congestion [1].

Triprolidine hydrochloride (TRI), an alkylamine derivative, is a sedating antihistamine with antimuscarinic and mild sedative effects. It is used for the symptomatic relief of allergic conditions including urticaria and rhinitis, and in pruritic skin disorders [1]. It is often used in combination with pseudoephedrine hydrochloride for rhinitis and in other compound preparations for the symptomatic treatment of coughs and the common cold [1].

The chemical structures of triprolidine and pseudoephedrine are shown in Figure 1.



Triprolidine (TRI) **Pseudoephedrine (PSE)**

Fig 1: Chemical structures of triprolidine and pseudoephedrine

The combination of TRI and PSE in tablets and syrup dosage form is official in the United State Pharmacopeia, normal phase HPLC method on silica column using mixture of alcohol and 0.4 % ammonium acetate solution (17:3 v/v) as mobile phase , with ultraviolet detection at 254 nm was employed for the determination of the two analytes [2]. Literature review revealed that only few methods have been developed for the determination of the two drugs combination, first derivative spectrophotometry and high performance liquid chromatography [3], partial least-squares multivariate calibration [4], second order derivative spectrophotometry [5], proportional isoabsorptive point spectrophotometric method [6], ratio spectra derivative spectrophotometry, derivative spectrophotometry and Vierordt's method [7].

The aim of the present work was to develop a simple, sensitive and accurate spectrophotometric method for the simultaneous determination of pseudoephedrine and triprolidine in bulk and tablet dosage form.

2. Experimental

2.1 Materials and Instruments

Pseudoephedrine HCl and triprolidine HCl working standards (99.6% and 99.5%, respectively) were

kindly provided by Blue Nile Pharmaceuticals, Sudan. Trifed tablets (Al-Hikma Pharmaceutical Industry- Jordon): labeled to contain 60mg of pseudoephedrine hydrochloride and 2.5mg of Triprolidine hydrochlorides were purchased from local market.

Hydrochloric acid analytical grade was purchased from Scharlau Chemie, Spain.

Hydrochloric acid solution 0.1 M was used as a diluent and solvent throughout the analysis.

UV spectrophotometric studies were carried out on Shimadzu UV-1800 (Koyoto, Japan).

2.2 Samples and standard solutions preparation

2.2.1 Stock standard solutions

Stock standard solutions of TRI (160 µg/ml) and PSH (3800 µg/mL) were prepared by accurately weighing and dissolving about 8 mg TRI and 190 mg PSE into two separate 50 ml volumetric flasks with 0.1N HCl.

2.2.2 Linearity standards

Separate linearity standards of two analytes were prepared by proper dilution of suitable aliquots from their corresponding stock standard solutions with 0.1 HCl to give concentration in the range of (6.4-32 µg/ml) and (152-760 µg/ml) for TRI and PSE, respectively. Absorbance values were measured at 257 nm and 290 nm. The absorbance values obtained at 257 nm and 290 nm were plotted against the corresponding TRI and PSE concentrations.

2.2.3 Sample preparation

A total of twenty tablets were accurately weighed, powdered and mixed well. A quantity of the resulted powder equivalent to one tablet was weighed and transferred into a 100 ml volumetric flask , the final volume was adjusted with 0.1 N HCl. The solutions were sonicated for 15 min then filtered using 0.45 µ filter.

2.2.4 Laboratory synthetic mixtures

Five laboratory synthetic mixtures containing different amounts of TRI and PSE were prepared by proper dilution of different aliquot volumes from their standards stock solutions in 50 ml volumetric flasks using 0.1 N HCl.

2.3 Procedure

2.3.1 Estimation of Wavelengths

Five ml of each stock standard solution were transferred to a separate 25 ml volumetric flasks. The volumes of the above solutions were completed to marks using 0.1 M HCl. The resultant solutions were scanned between 220-320 nm ranges. The wavelengths were determined and their corresponding specific absorbance was calculated.

3. Results and discussion

3.1 Estimation of analytical wavelengths

The UV spectrum of triprolidine showed absorbance at two wavelengths, namely 257 nm and 290 nm with corresponding specific absorptivity values 201.7 and 284.12, respectively. Triprolidine was found to interfere with pseudoephedrine absorbance only at the wavelength 257 nm; where pseudoephedrine has specific absorptivity value of 8.10 (Fig. 2).

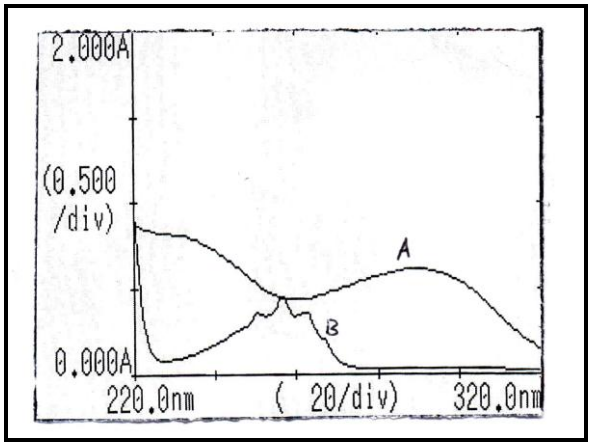


Figure 2: Absorption spectra of Triprolidine HCl (A) 30 µg/ml and Pseudoephedrine HCl (B) 750 µg/ml

These findings were used to calculate the concentration of the two analytes. Since at 290 nm the absorbance of triprolidine is free from interference by pseudoephedrine; its concentration was calculated from equation 1.

$$C_{TRI} = A_{TRI} / A^{1\%}_{1\,cm}\, l$$

Eq.1 (at 290 nm)

At the wavelength of 257 nm the sample absorbance is the sum of the absorbance due to pseudoephedrine plus the contribution from triprolidine; accordingly it is possible to calculate the concentration of pseudoephedrine from the total absorbance at 257 nm using equation 2.

$$A_m = A^{1\%}_{1\,cm\ PSE}\, l\, C_{PSE} + A^{1\%}_{1\,cm\ TRI}\, l\, C_{TRI}$$

and,

$$A_{PSE} = A_m - A_{TRI}$$

$$C_{PSE} = (A_m - (A^{1\%}_{1\,cm\ TRI}\, l\, C_{TRI})) / A^{1\%}_{1Ccm\ PSE}$$

Eq. 2 (at 257 nm)

Where: A_m is the absorbance of the mixture; $A^{1\%}_{1\,cm}$ is the specific absorptivity for TRI and PSE; ***l*** is the cell path length (= 1 cm).

3.2 Linearity

Beer's law was obeyed in the concentration range (6.4-32 µg/ml) and (152-760 µg/ml) for TRI and PSE, respectively. Table 1 reveals the statistical data for the regression equations of the proposed method.

Table 1: Regression analysis data

	PSE	TRI	
Wavelength	**257 nm**	**257 nm**	**290 nm**
Concentration range (µg/ml)	152-760	6.4-32	
Slope (b)	0.00081	0.0201	0.0284
Intercept (a)	0.0046	-0.0142	-0.0021
Correlation coefficient (r^2)	0.9996	0.9997	0.9996
Standard deviation of the slope (s_b)	$8.11x10^{-6}$	0.0002	0.0002
Standard deviation of the intercept (s_a)	0.002	0.0029	0.0035

3.3 Precision

The precision of the developed method was evaluated by the results obtained from between-days (intermediate precision) and within-day data (repeatability) of six replicate determinations of samples containing 100% of their corresponding expected concentrations in the pharmaceutical product. The relative standard deviations (RSD) of their recoveries were determined. The observed RSD levels (Table 2), which were below 2%, were considered satisfactory. For verification of precision the process was repeated on another day using fresh reagents and samples (intermediate precision). This evidenced that the outcome of the determination was statistically similar regardless the day of the assay and the reagents preparation.

Table 2: Precision of the proposed method

Parameter	**% of label claim**			
	Triprolidine		**Pseudoephedrine**	
	Day 1	**Day 2**	**Day 1**	**Day 2**
mean (n =6)	102.68	103.00	102.79	102.94
STDEV	0.75	0.72	0.70	0.93
RSD%	0.73	0.76	0.68	1.02

3.4 Recovery

The proposed method was applied for the determination of the two analytes in five laboratory synthetic mixtures containing different amounts of TRI and PSE. The mean content percent of five independent analyses for TRI and PSE were found to be 98.60 ± 0.65% and 101.28 ± 1.09%, respectively; n=5 (Table 3).

Table 3: Recovery data of the synthetic mixtures

Triprolidine HCl µg/ml		**% Content**	**Pseudoepherdine HCl µg/ml**		**% Content**
Theoretical	**Actual**		**Theoretical**	**Actual**	
18.13	17.83	98.31	242.28	248.93	102.75
13.60	13.37	98.34	323.04	324.80	100.55
13.60	13.36	98.21	242.28	247.49	102.15
18.13	18.09	99.77	323.04	324.52	100.46
22.67	22.30	98.37	403.80	405.87	100.51
mean		98.60	**mean**		101.28
RSD%		0.65	**RSD%**		1.09

The validity of the method was further assessed by comparing the statistical results obtained with those of the official USP liquid chromatography method. As the calculated t- values were less than tabulated ones (n =6, P=0.05), the result of the developed method can be considered as accurate and precise as the official liquid chromatographic method (Table 4).

Table 4: Results of the proposed method compared to the official method

		% content ± sd	t - calculated (t - tabulated)
Proposed method	Triprolidine	102.68 (0.75)	1.69 (2.57)
	Pseudoephedrine	102.79 (0.70)	2.36 (2.57)
Official method	Triprolidine	102.00 (0.69)	
	Pseudoephedrine	101.50 (0.68)	

4. Conclusion

The proposed method was proved to be simple, selective, precise and sensitive for the determination of triprolidine and pseudoephedrine in bulk form and tablet forms. Statistical and analytical validation of the results, using λ = 257 and 290 nm, confirmed that the simultaneous determination could be used as an alternative method for the routine analysis of both drugs in quality control laboratories.

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