

Spectrophotometric and High Performance Liquid Chromatographic Determination (HPLC) of Triprolidine and Pseudoephedrine Hydrochloride in Tablet Dosage Form

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ABSTRACT

First order derivative spectrophotometric method and high performance liquid chromatographic method were developed for the determination of Triprolidine and Pseudoephedrine Hydrochloride in tablet dosage form. In UV-Spectrophotometric method, estimation of Triprolidine and Pseudoephedrine Hydrochloride was carried out at the wavelength selected 246.20 nm and 263.50 nm for First order Derivative method. Calibration curves were linear in the range of 2-10 $\mu\text{g ml}^{-1}$ for Triprolidine and 48-240 $\mu\text{g ml}^{-1}$ for Pseudoephedrine Hydrochloride in derivative method. Correlation coefficient found to be close to 0.9950 for both the drugs. Accuracy for both the drugs was in the range of 99-101.5%. A simple liquid chromatographic assay has been developed for the determination of Triprolidine and Pseudoephedrine Hydrochloride. A C_{18} (250 \times 4.6 mm, 5 μm) column was used with a mobile phase consisting of Methanol: Water (80: 20 v/v) (pH adjusted to 3.0 with ortho phosphoric acid) at a flow rate of 1.0 ml min⁻¹. Quantitation was achieved with UV detection at 246.20 nm based on the peak height ratios. Beer's law was obeyed in a concentration range of 5-25 $\mu\text{g ml}^{-1}$ for Triprolidine and 120-600 $\mu\text{g ml}^{-1}$

for Pseudoephedrine Hydrochloride and the regression line equation was derived with a correlation coefficient of 0.9999 and 0.9998 for Triprolidine and Pseudoephedrine Hydrochloride. The proposed procedures were successfully applied to the determination of Triprolidine and Pseudoephedrine Hydrochloride in bulk and tablet form, with high percentage of recovery, good accuracy and precision.

Key words: Triprolidine, Pseudoephedrine Hydrochloride, Derivative method, HPLC method, Tablets.

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INTRODUCTION

Triprolidine, 2-[(1E)-1-(4-methylphenyl)-3-(pyrrolidin-1-yl)prop-1-en-1-yl] pyridine (Figure 1), Anti allergic, Histamine H1 Antagonist that blocks the action of endogenous histamine, which subsequently leads to temporary relief of the negative symptoms brought on by histamine. It is used for the treatment of Seasonal or perennial allergic rhinitis or non allergic rhinitis, conjunctivitis and mild uncomplicated allergic skin manifestations of urticaria and angioedema.^{1,2}

Pseudoephedrine Hydrochloride, (1S,2S)-2-(methylamino)-1-phenylpropan-1-ol (Figure 2), it acts as Vasoconstrictor, Adrenergic Agents, Sympathomimetics, Bronchodilator Agents. It is indicated for the treatment of patients with nasal congestion, sinus congestion, and vasomotor rhinitis.^{3,4}

Tripolidine is official in Indian Pharmacopoeia 2010⁵ and British Pharmacopoeia 2009⁶ and United State Pharmacopoeia⁷ and describes Liquid Chromatographic method for its estimation and a literature survey reveals that HPLC⁸⁻¹² methods has been developed for its estimation in alone or in combination with other drugs in plasma and pharmaceutical dosage forms. Pseudoephedrine Hydrochloride is official in Indian Pharmacopoeia 2010;¹³ British Pharmacopoeia 2009¹⁴ and United State Pharmacopoeia¹⁵ and HPLC method given for the assay of Pseudoephedrine Hydrochloride. Various HPLC¹⁶⁻²¹ and HPTLC²² methods have been reported for the determination of Pseudoephedrine Hydrochloride alone or in combination with other active pharmaceutical agents in dosage forms or in biological fluids. Combined dosage forms of Triprolidine and Pseudoephedrine Hydrochloride are official in United State Pharmacopoeia²³ and HPLC method is given for their simultaneous estimation. Literature survey reveals that HPLC methods²⁴⁻²⁷ and UV-spectrophotometric method²⁸⁻²⁹ has been reported for simultaneous estimation of Triprolidine and Pseudoephedrine Hydrochloride.

The purpose of present study was to develop and validate new spectrophotometric and HPLC method for simultaneous determination of Triprolidine and Pseudoephedrine Hydrochloride in tablet dosage form.

MATERIALS AND METHODS

Instrumentation

A double beam, UV-visible spectrophotometer (Simadzu-1800, Software -UV Probe, Version 2.42) with 1 cm matched quartz cells was used. The spectral band width was 2 nm and the wavelength scanning speed was medium.

The HPLC (Agilent SHIMADZU) instrument was equipped with a C_{18} (250 \times 4.6 mm, 5 μm) column, an auto injector, UV- Detector and LC Solution software.

Materials

Pharmaceutical grade of Triprolidine and Pseudoephedrine Hydrochloride used as reference standard were supplied by Triveni Chemicals, Vapi. Combined tablet formulation (Recofast) was purchased from local market. All other reagents used were AR grade and HPLC grade. AR grade methanol acquired from S.D. Fine Chemicals. Distilled water (HPLC grade- Merk, Renkem), Acetonitrile (HPLC grade- Merk, Renkem), Methanol (HPLC grade- Merk, Renkem), Ortho phosphoric acid (S.D. Fine Chemicals) were used for analysis.

Chromatographic conditions

The mobile phase was prepared by mixing methanol and water in the ratio of 80:20 v/v and pH 3.0 adjusted with ortho phosphoric acid. It was filtered through 0.45 μm membrane filter. All determinations were

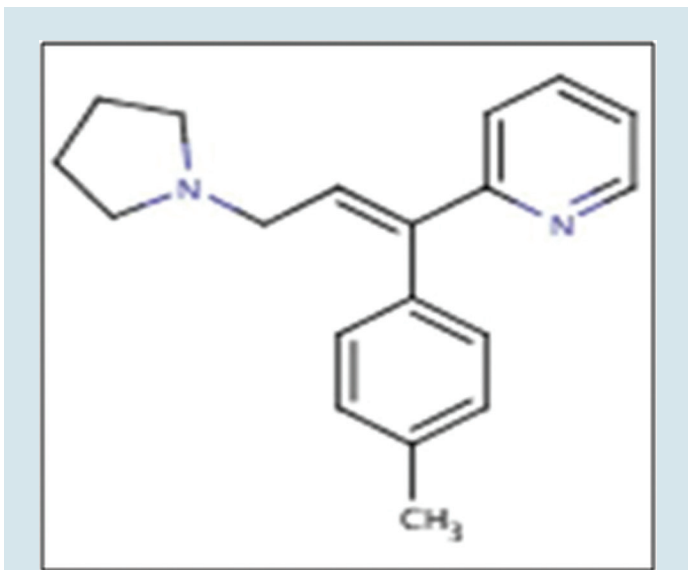


Figure 1: Structure of Triprolidine

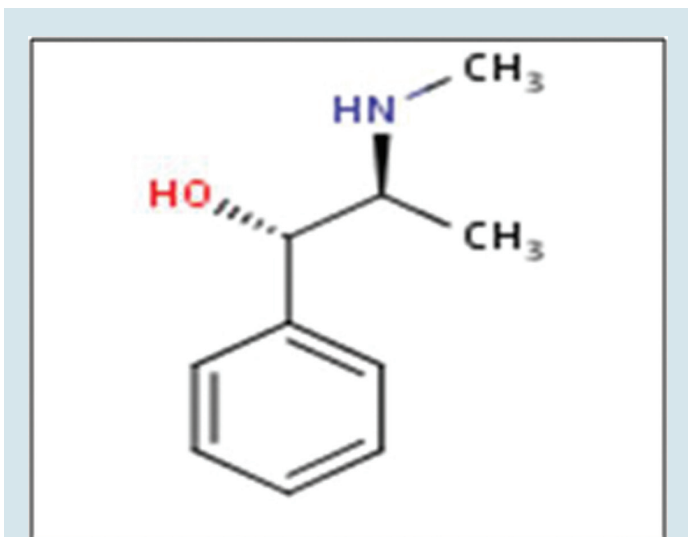


Figure 2: Structure of Pseudoephedrine Hydrochloride

performed at ambient temperature (25°C) using C₁₈, 250×4.6 mm, 5 μm, reverse phase column (Agilent SHIMADZU). The column effluent was monitored at 246.20 nm, which represents the wavelength of maximum absorbance of Triprolidine and Pseudoephedrine Hydrochloride. The injection volume was 10 μl with a flow rate of 1 ml min⁻¹.

Standard solutions and calibration graphs for spectrophotometric measurements

First Order Derivative Method

A stock solution was prepared by dissolving Triprolidine and Pseudoephedrine Hydrochloride in methanol and dilution was made by Methanol to obtain a concentration of 1000 μg ml⁻¹ and 1000 μg ml⁻¹ of Triprolidine and Pseudoephedrine Hydrochloride respectively. The standard solutions were prepared by dilution of the stock solution in Methanol to reach concentration ranges of 2–10 μg ml⁻¹ and 25–250 μg ml⁻¹ for Triprolidine and Pseudoephedrine Hydrochloride respectively for First order derivative method. Each solution was scanned between 200 - 400 nm. Wavelengths were selected from the overlay spectra of Triprolidine and Pseudoephedrine Hydrochloride. The absorbance of the solutions was measured at 246.20 nm and 263.50 nm against methanol as a reagent

blank. The concentrations versus Absorbance were plotted in order to obtain the calibration graphs.

Standard solutions and calibration graphs for chromatographic procedure (HPLC)

Standard solutions of Triprolidine and Pseudoephedrine Hydrochloride containing concentration range of 5–25 μg ml⁻¹ for Triprolidine and 120–600 μg ml⁻¹ for Pseudoephedrine Hydrochloride were prepared in the mobile phase. Triplicate 10 μl injections were made for each concentration and the peak height ratio of each concentration were plotted against the corresponding concentrations to obtain the calibration graph.

Sample preparation

A total of 20 tablets containing Triprolidine and Pseudoephedrine Hydrochloride as the active ingredients were weighed and finely powdered. The powder equivalent to 1 mg of Triprolidine and 60 mg of Pseudoephedrine Hydrochloride was taken in 100 ml volumetric flask and dissolved in mobile phase. The volume was made up to mark and the solution was filtered through 0.45 μ membrane filter. The appropriately diluted solution was analyzed under optimized chromatographic conditions. The areas of resulting peak were measured at 246.20 nm. The peak-height ratios were used for the determination of Triprolidine and Pseudoephedrine Hydrochloride in each sample.

For First order derivative spectrophotometric method, a 1 ml of this solution was diluted to 10 ml with methanol and in another flask 0.6 ml of this solution was further diluted to 10 ml with methanol. Absorbance of the resulting solution was measured at 246.20 nm and 263.50 nm against methanol. The concentration of Triprolidine and Pseudoephedrine Hydrochloride can be obtained as,

$$dA/d\lambda = dA/dt / (d\lambda/dt) = (dA/dt)(1/C)$$

VALIDATION PROCEDURE

System suitability

The typical values for evaluating system suitability of a chromatographic procedure include the RSD <1%, tailing factor <2 and theoretical plates >2000. The determination of system suitability of analytical method was accomplished by assaying six samples of Triprolidine and Pseudoephedrine Hydrochloride. The sample concentration of Triprolidine and Pseudoephedrine Hydrochloride used in this analysis was 5–25 μg/ml and 120–600 μg/ml, respectively. The retention time, peak area, theoretical plates and tailing factor were evaluated for system suitability.

Sensitivity

The limit of detection (LOD) and quantification limit (LOQ) were determined by gradually diluting the sample and analysing by the proposed method. The signal/noise ratio (S/N) was determined for each tested strength. The typical S/N ratio recommended by the International Conference on Harmonization (ICH) is 3/1 and 10/1 for LOD and LOQ, respectively.

Calibration curve

The above-mentioned calibration standards were analysed for determining linearity. The sample strengths ranged from 5–25 μg ml⁻¹ and 120–600 μg ml⁻¹ for Triprolidine and Pseudoephedrine Hydrochloride respectively for HPLC method and 2–10 μg ml⁻¹ and 48–240 μg ml⁻¹ of Triprolidine and Pseudoephedrine Hydrochloride for derivative method. The regression analysis was accomplished by slope, intercept and correlation coefficient (r²).

Accuracy and precision

The accuracy was determined by percent recovery method. Furthermore, precision (inter-day variance and intra-day variance) were determined

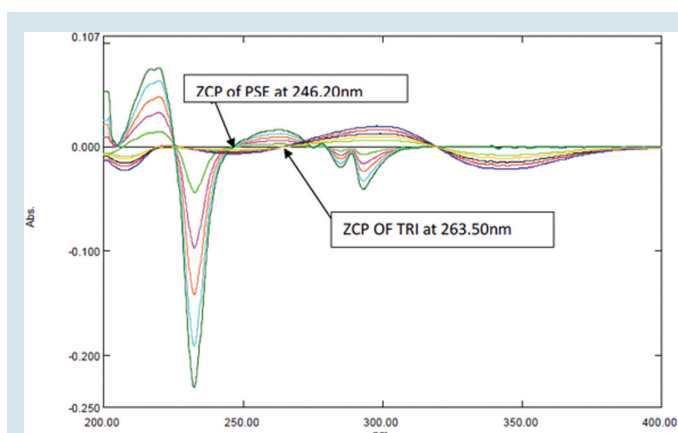


Figure 3: Overlay UV-spectra of Triprolidine and Pseudoephedrine Hydrochloride. (First order Derivative)

by assaying samples over a period of 1 day and 3 days, respectively. The standard concentrations used for this study were 15, 20, and 25 $\mu\text{g ml}^{-1}$ for Triprolidine and 360, 480, and 600 $\mu\text{g ml}^{-1}$ for Pseudoephedrine Hydrochloride for HPLC method and for derivative method the concentrations used were 6, 8 and 10 $\mu\text{g ml}^{-1}$ and 144, 192 and 240 $\mu\text{g ml}^{-1}$ for Triprolidine and Pseudoephedrine Hydrochloride respectively.

Robustness

The influence of slight deliberate changes in chromatographic conditions such as column temperature, flow rate of mobile phase and pH of mobile phase on the retention time and peak area were observed one by one. The test was performed in triplicate for each set of conditions. The standard concentrations of Triprolidine and Pseudoephedrine HCl used in this analysis were 10 $\mu\text{g/ml}$ and 240 $\mu\text{g/ml}$, respectively. Data for Robustness is given in Table 6a and 6b for Triprolidine and Pseudoephedrine Hydrochloride.

RESULTS AND DISCUSSION

First Order Derivative method

Tablet powder was dissolved in methanol. To determine wavelength for measurement, standard spectra of Triprolidine and Pseudoephedrine Hydrochloride were scanned between 200-400 nm against methanol. Absorbance of Pseudoephedrine Hydrochloride measured at Zero

Table 1: Results for system suitability test.

Parameters	Data obtained	
	Triprolidine	Pseudoephedrine Hydrochloride
Theoretical plates per column	2453	4563
Symmetry factor/Tailing factor	1.31	1.43
Resolution	5.876	

crossover point of Triprolidine, that is 263.50 nm and absorbance of Triprolidine was measured at Zero crossover point of Pseudoephedrine Hydrochloride, that is 246.20 nm. Overlain spectra of Triprolidine and Pseudoephedrine Hydrochloride are presented in Figure 3.

Chromatographic procedure (HPLC)

A reversed phase HPLC method was developed to provide a specific procedure suitable for rapid quality control of Triprolidine and Pseudoephedrine Hydrochloride tablet dosage form. A mobile phase consisting of Methanol: Water (80: 20) and pH 3.0 adjusted with ortho phosphoric acid, was chosen after several trials with acetonitrile: water and methanol: water. The apparent pH of the aqueous phase was adjusted to 3.0 using orthophosphoric acid. The above described chromatographic system allowed an adequate resolution (R_s 5.876) between Triprolidine (t_r 4.03) and Pseudoephedrine Hydrochloride (t_r 6.2) in a reasonable time (Figure 5) (R_s , resolution; t_r , retention time). The applied analytical conditions produced the peaks with suitable peak symmetry (<2).

The typical conditions for system suitability of an analytical method encompass the relative standard deviation (RSD) $<1\%$, peak symmetry <2 and theoretical plates >2000 . The results of system suitability of present chromatographic method are described in Table 1. The peak area, retention time, tailing factor and theoretical plates were within the recommended limits. Therefore, the method was considered as suitable for quantitative determinations a linear calibration graph ($Y = 13514x + 42710$, $r^2 = 0.9996$; $n=3$, for Triprolidine and $Y = 936.9x + 110140$, $r^2 = 0.9985$; $n=3$ for Pseudoephedrine Hydrochloride) was obtained over the working concentration range of 5-25 $\mu\text{g ml}^{-1}$ for Triprolidine and 120-600 $\mu\text{g ml}^{-1}$ for Pseudoephedrine Hydrochloride.

The specificity and selectivity of the HPLC system were ascertained by a separate chromatographic analysis of either the excipient mixtures or sample; no interfering peaks at the retention times of Triprolidine and Pseudoephedrine Hydrochloride peaks were observed.

Table 2: Regression and analytical parameters for estimation of two drugs by Derivative ratio and HPLC method.

Parameter	HPLC method		Derivative method	
	TRI	PSE	TRI	PSE
Wavelength(nm)	246.20	246.20	246.20	263.5
Concentration range($\mu\text{g ml}^{-1}$)	5-25	25-250	2-10	25-250
Intercept	13514	936.9	0.001	0.002
Slope	42710	110140	0.001	0.001
Correlation coefficient (r^2)	0.9996	0.9985	0.995	0.995
Regression equations	$13514x + 42710$	$936.9x + 110140$	$0.002x + 0.001$	$0.001x + 0.001$
Repeatability (%RSD, n=6)	1.891	1.694	0.525	0.330
Intraday precision (%RSD, n=3)	1.506	0.324	0.179- 0.893	0.080- 0.394
Interday precision (%RSD, n=3)	1.435	0.719	0.932- 1.881	0.308- 1.376
Accuracy (%recovery)	100.2	100.04	99-101.5	99.0-100.5
LOD ($\mu\text{g ml}^{-1}$)	0.384	0.281	0.18	0.181
LOQ ($\mu\text{g ml}^{-1}$)	1.170	0.938	0.547	0.547

Table 3: Data for Intraday and Interday precision.

Drug	HPLC method				Derivative method				
	Amt. ($\mu\text{g ml}^{-1}$)	% RSD		Amt. ($\mu\text{g ml}^{-1}$)	% RSD		Amt. ($\mu\text{g ml}^{-1}$)	% RSD	
		Intraday	Interday		Intraday	Interday		246.20 nm	263.50 nm
TRI	15	0.362	0.470	6	0.809	-	1.634	-	-
	20	1.131	0.952	8	0.370	-	0.783	-	-
	25	0.040	0.040	10	0.162	-	1.021	-	-
PSE	360	0.153	0.440	144	-	0.782	-	1.876	-
	480	0.021	1.328	192	-	0.368	-	1.228	-
	600	0.450	0.3913	240	-	0.215	-	0.533	-

Table 4: Results of recovery study by HPLC and UV methods. (n=3)

Method	Drug	Amt. present ($\mu\text{g ml}^{-1}$)	Amt. added ($\mu\text{g ml}^{-1}$)	Amt. recovered ($\mu\text{g ml}^{-1}$)	% Recovery
HPLC Method	TRI	5	4	4.02	101.65
		5	5	5.03	100.75
		5	6	5.97	99.71
	PSE	120	216	217.2	101.2
		120	240	239.1	99.20
		120	264	263.0	99.98
UV method	TRI 246.20nm	4	3.2	3.18	99.38
		4	4	4.04	101.11
		4	4.8	4.79	99.08
	PSE 263.5nm	120	96	96.09	100.56
		120	120	119	99.90
		120	144	263.92	99.68

Table 5: Assay of marketed formulation Recofast by HPLC and UV methods

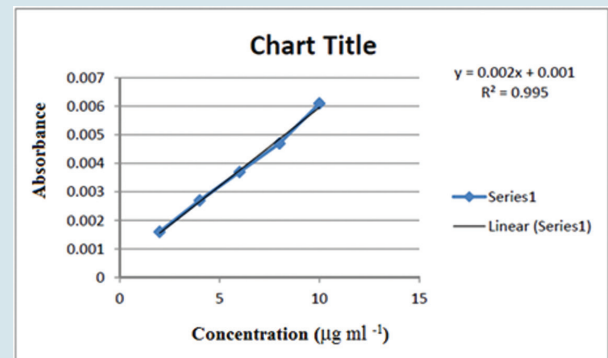
Assay	Marketed formulation	Drug	Label claimed (mg/tab)	Amt. found (mg/tab)	% Label claimed	SD
HPLC Method	RA5466	TRI	10	2.50	100.33	0.112
		PSE	240	59.92	99.03	0.699
	RC8799	TRI	10	2.52	101.21	0.119
UV method	REC765	PSE	240	60.33	101.06	0.581
		TRI	1	2.52	100.16	0.131
	REC6757	PSE	24	62.32	99.76	0.409
		TRI	1	2.75	98.33	0.131
		PSE	24	58.35	101.13	0.098

Table 6a: Robustness data for Triprolidine.

Parameters	Mean area \pm S D	%RSD
Flow rate + 2	245565.7 \pm 1685.98	1.472
Flow rate - 2	453741.3 \pm 2272.85	1.608
Mobile phase + 2	286574 \pm 2260.38	0.617
Mobile phase - 2	456248.7 \pm 4933.38	1.34
pH + 2	257916 \pm 4338.90	1.202
pH - 2	471661.7 \pm 3225.32	0.667

Table 6b : Robustness data for Pseudoephedrine Hydrochloride.

Parameters	Mean area \pm S D	%RSD
Flow rate + 2	560687.7 \pm 5070.16	1.533
Flow rate - 2	540288 \pm 1345.76	0.567
Mobile phase + 2	557737.7 \pm 2783.24	1.65
Mobile phase - 2	538028.7 \pm 1158.91	1.342
pH + 2	516424.7 \pm 3196.71	0.954
pH - 2	536300 \pm 3510.60	1.56

**Figure 4a:** Calibration curve for Triprolidine at 246.20 nm in methanol

The LOD and LOQ in accordance with the ICH guidelines is 3/1 and 10/1, respectively. LOD and LOQ values for Triprolidine and Pseudoephedrine Hydrochloride for Derivative method and HPLC method are given in Table 2.

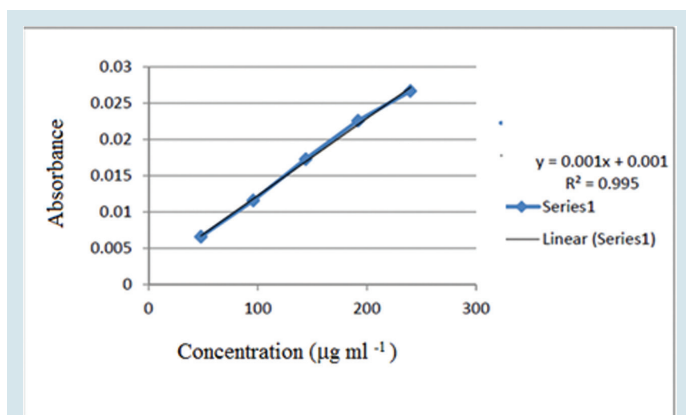


Figure 4b: Calibration curve for Pseudoephedrine Hydrochloride at 263.50 nm in methanol

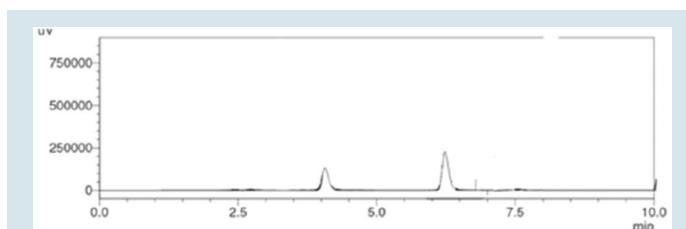


Figure 5: Typical Chromatogram of Triprolidine and Pseudoephedrine Hydrochloride

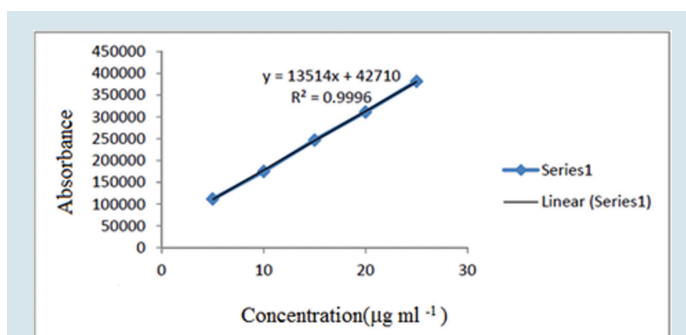


Figure 6a: Calibration curve for Triprolidine in HPLC method

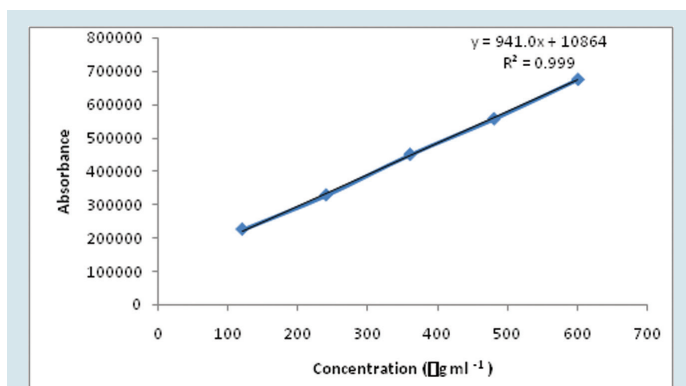


Figure 6b: Calibration curve for Pseudoephedrine HCl in HPLC method

Each calibration curve was constructed with five standard strengths (Figure 3). For Derivative method, the calibration curve of Triprolidine was made with 2, 4, 6, 8 and 10 $\mu\text{g ml}^{-1}$ concentrations (Figure 4a). Similarly, the concentrations used in the formation of calibration curve of Pseudoephedrine Hydrochloride were 48, 96, 144, 192 and 240 $\mu\text{g ml}^{-1}$ (Figure 4b). For HPLC method, A typical Chromatogram for Triprolidine and Pseudoephedrine shown in Figure 5 and the calibration curve of Tripro-

lidine was made with 5, 10, 15, 20 and 25 $\mu\text{g ml}^{-1}$ concentrations (Figure 6a). Similarly, the concentrations used in the formation of calibration curve of Pseudoephedrine Hydrochloride were 120, 240, 360, 480 and 600 $\mu\text{g ml}^{-1}$ (Figure 6b). The regression analysis is displayed in Table 2. The correlation coefficient (r^2) was close to 0.9999 for both Triprolidine and Pseudoephedrine Hydrochloride.

The results of accuracy and precision (inter-day variance and intra-day variance) are shown in Table 3 and 4. For accuracy, all the recovery values were within $\pm 5\%$. By Derivative method, the mean recovery value of Triprolidine and Pseudoephedrine Hydrochloride was 99-101.5% at 246.20 nm and 99.0-100.5 % at 246.50 nm. In HPLC method the recovery values of Triprolidine and Pseudoephedrine Hydrochloride was 100.2% and 100.04 %. For inter-day and intra-day variance assessment %RSD was calculated. All the samples exhibited RSD values $< 1\%$ confirming that the analytical method was precise.

Robustness study was carried out by making minor changes in conditions like composition of mobile phase, flow rate of mobile phase and pH of mobile phase. No substantial variances were observed in the retention time and peak area of each component when the chromatographic conditions were slightly changed one by one. Moreover, the RSD for each value was $< 1\%$. Thus, the proposed method was considered as robust.

Statistical evaluation of the developed procedures

The HPLC method was chosen as the analytical reference method. Derivative spectrophotometric procedures were compared with HPLC. The slopes, intercepts and linearity of each calibration graph were calculated and summarized in Table 2. The order of linearity for the calibration graphs in the ranges stated in Table 2 for the different analytical method was: Derivative Method/HPLC. The concentration ranges, detection limits and quantitation limits are summarized in Table 2. The lowest detection limit calculated was obtained for absorbance ratio method indicating the highest sensitivity. Relative sensitivities, based on detection limits, were calculated with respect to the chromatographic method. The order of sensitivity for this method was: Derivative Method\HPLC. Commercially available tablets were analyzed using the HPLC and the Derivative spectrophotometric methods. The results obtained were summarized in Table 5. No significant differences were found between the results obtained by the HPLC and the spectrophotometric procedures, for the same batch at the 95% confidence level. Statistical comparison was done on assay results obtained from UV and HPLC methods for marketed formulation (Recofast) by using student's t-test. Calculated values for t-test were 1.190 and 0.206 for TRI and PSE respectively which is less than t_{critical} value (12.706) indicating that there was no significant difference between the HPLC method and UV method.

CONCLUSION

The HPLC method and the spectrophotometric (First Order Derivative) method were found to be reproducible and accurate in the analysis of Triprolidine and Pseudoephedrine Hydrochloride in pharmaceutical tablets. Under the experimental conditions, mentioned above, the First Order Derivative method was the most sensitive method; however, better selectivity was obtained with the HPLC method. All the proposed methods were linear with good reproducibility and sensitivity. In general, all the proposed methods can be used for the routine analysis of Triprolidine and Pseudoephedrine Hydrochloride in bulk and tablet dosage form.

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ABBREVIATIONS USED

HPLC: High Performance Liquid Chromatography; **UV:** Ultra violet; **HPTLC:** High performance thin layer chromatography; **TRI:** Triprolidine; **PSE:** Pseudoephedrine Hydrochloride; **ICH:** International Conference of Harmonization; **S/N:** Signal to noise; **RSD:** Relative standard deviation.

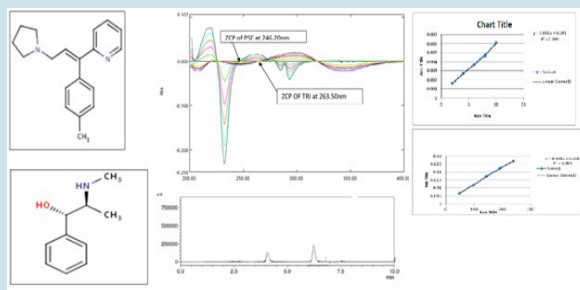
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SUMMARY

- First order derivative spectrophotometric method is developed for the determination of Triprolidine and Pseudoephedrine Hydrochloride in tablet dosage form at 246.20 nm and 263.50 nm.
- A simple liquid chromatographic assay method has been developed for the determination of Triprolidine and Pseudoephedrine Hydrochloride. A C₁₈ (250×4.6 mm, 5 µm) column was used with a mobile phase consisting of Methanol: Water (80: 20 v/v) (pH adjusted to 3.0 with ortho phosphoric acid) at a flow rate of 1.0 ml min⁻¹. UV detection was at 246.20 nm based on the peak height ratios.
- The proposed procedures were successfully applied to the determination of Triprolidine and Pseudoephedrine Hydrochloride in bulk and tablet form, with high percentage of recovery, good accuracy and precision.

PICTORIAL ABSTRACT



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