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Analytical techniques for the estimation of Trospium chloride in capsule dosage form by spectrophotometric method

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Abstract
For the determination of Trospium Chloride in pure formulations and its pharmaceutical formulations, a simple UV-spectrophotometric method was developed. Trospium Chloride exhibited maximum absorption at 280 nm in ethanol and obeyed linearity in the concentration range of 10-70 µg/ml. The method proposed was validated statistically. With good accuracy, all the proposed methods are simple, selective, reproducible, sensitive and precise. Some of the methods were proved to be superior to most of the reported methods. Many of these suggested prediction methods for chosen drugs, such as Trospium Chloride, have been successfully implemented either in bulk or in prescription formulations. The suggested methods can be used in bulk and prescription dosage formulations as alternative methods to the recorded ones for the routine determination of selected drugs in the sample.

Keywords: Methanol, Capsule, UV Spectroscopy, Trospium Chloride

Introduction
UV-visible spectrophotometric methods that fall in the 200-380 nm wavelength region and fluorimetric methods are very simple, inexpensive, and easy to estimate bulk-form drugs and their formulations. The drawbacks of certain analytical colorimetric or fluorimetric approaches lie in the chemical reaction on which the systems are based rather than the available instruments. Many of the reactions involve a certain drug's color or fluorescence are very selective or may be made selective by adding masking agents, regulating pH, using solvent extraction methods, changing oxidation states or previous elimination of intervening ingredients with the assistance of separate chromatographic ingredients [1, 2, 3]. Trospium Chloride (TROS) is a muscarinic antagonist and is available for oral administration in 60 mg strength capsules. Chemically, it is spiro [8-azoniabicyclo [3.2.1] octane-8, 1'-pyrrolidinium],-3-[(hydroxy diphenyl lacetyl)oxy]-, chloride, (1R, 3r, 5S).The drug is official in British Pharmacopoeia. TROS blocks acetylcholine's role on muscarinic receptors in cholinergically innervated organs like the bladder. Its parasympatholytic activity lowers the bladder's smooth muscle tonus. At therapeutic doses, receptor assays revealed that TROS has negligible affinity for nicotinic receptors as opposed to muscarinic receptors. According to the literature review, few computational approaches for estimating TROS, such as UV-Visible analysis, have been reported. [4, 5, 6]. The aim of the approach proposed is to establish simple and precise methods for the determination of TROS in pharmaceutical dosage forms using the UV-Spectrophotometry method. All of these findings have demonstrated the need for a fast and sensitive quality-control study of TROS-containing pharmaceutical formulations. Since these methods are costly, we have tried to establish a more reliable, convenient and economical spectrophotometric approach with greater precision, specificity and sensitivity for the study of TROS in bulk and dosage types.

Materials and Methods
TROS was obtained as gift sample from Elite chemicals and all reagents were purchased from SD Chemicals Chennai. There was an analytical grade of all materials and reagents used.

Method Development
For the identification of TROS in pure form and its pharmaceutical formulation, a simple UV-Visible Spectrophotometric method was developed. TROS demonstrated maximal ethanol absorbance at 280nm and obtained linearity in the 10 to 70 µg/ml concentration range. The method proposed was validated statistically.

Instrumentation: Analytical technologies ltd, Thermo scientific UV-Visible Spectrophotometric method was conducted using 1-cm quartz cells.

Selection of Solvent: Methanol was selected an ideal solvent for spectrophotometric analysis of TROS.

Scanning and Determination of Maximum Wavelength (λmax)
Various drug solutions (10µg/ml and 70µg/ml) in Methanol were scanned using UV-Visible spectrophotometers within the 200-380nm wavelength region against Methanol as blank in order to determine the wavelengths of maximum absorption (λmax) of the drug. The resulting spectrum was presented in Fig 1 and the absorption curve showed characteristic absorption maximum at 280 nm for TROS.

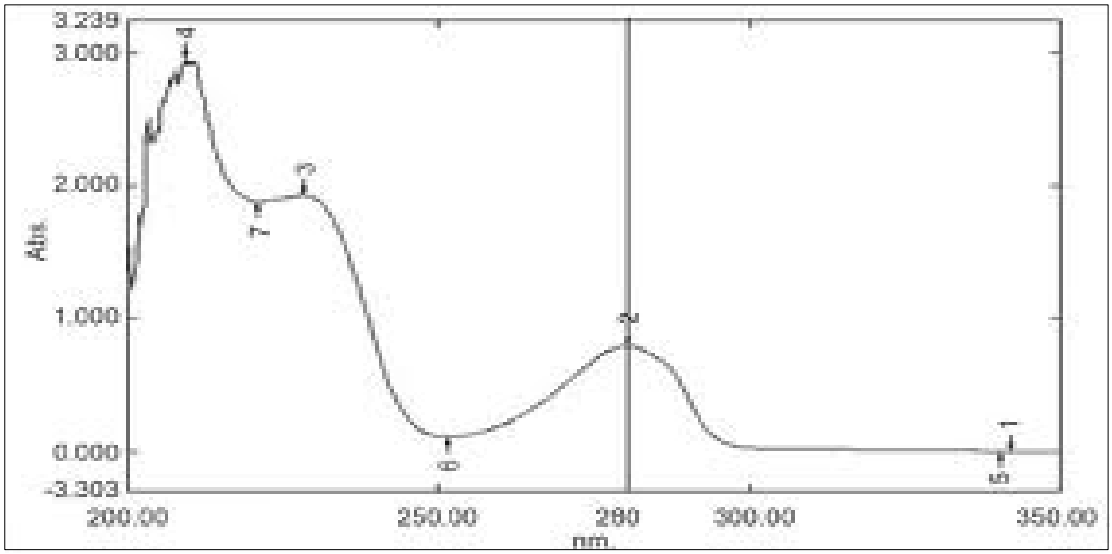

Fig 1: Absorption Spectrum of Trospium Chloride in Methanol

Preparation of Stock Solution

Standard stock solution of TROS was prepared by dissolving 10mg of TROS drug in 10ml of Methanol in 10ml of volumetric flask to get a concentration of 1mg/ml solutions.

Preparation of Working Standard Solutions and construction of standard graph

To achieve working quality solutions of 10ug/ml and 100ug/ml, the formulated stock solution was further diluted with Methanol. Different aliquots of TROS were taken and diluted to 10 ml with Methanol to create Beer's law plot for TROS to get the working normal solutions as shown in Table1. The absorbances of each solution were measured at lmax 280 nm against Methanol as blank. The results were shown in table1. The standard graph for TROS was plotted by taking concentration of drug on x-axis and absorbance on y-axis and was shown in Fig 2. The drug has obeyed Beer's law in the concentration range of 0.2-40ug/ml [7].

Estimation of Trospium Chloride in commercial 1formulations

For analysis of commercial formulations, 20 Tablets containing TROS were taken and powdered. The powder equivalent to 0.010g of TROS was taken in a 10ml volumetric flask, containing 7ml of Methanol and sonicated for 30 minutes. The volume was made up to 10ml with Methanol and filtered to get a solution of concentration 1000µg/ml. This was further diluted with Methanol to get a concentration within the linearity range and the absorbances were measured against the blank at 280 nm. The results were shown in Table 3.

Table 1: Linearity table of Trospium Chloride (pure drug) in Methanol at 244 nm

S.NO	Concentration(ug/ml)	Absorbances
1	10	0.107
2	20	0.173
3	30	0.248
4	40	0.345
5	50	0.421
6	60	0.486
7	70	0.572

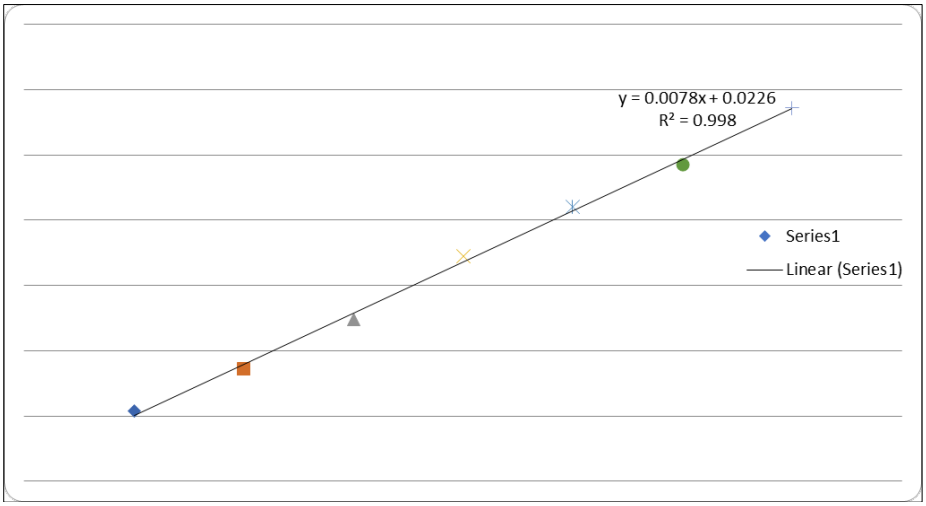

Fig 2: Linearity graph of Trospium chloride

Table 2: Optical characteristics of proposed method.

S.No	Parameter	Trospium Chloride
1	lmax (nm)	280 nm
2	Beer's Law limit (mg/ml)	10-70
3	Regression equation (Y)	0.0007x+0.022
4	Slope (a)	0.007
5	Intercept (b)	0.022
6	% Range of error 95% confidence limits 99% confidence limits	 0.0006025 0.000793
7	Correlation co-efficient	0.998

Validation

Precision: The precision of the proposed method was ascertained by actual determination of six replicates of fixed concentration of the drug within the Beer's range and finding out the absorbance's by the proposed method [8]. From this absorbance's Mean, Standard deviations, %R.S. D were calculated. The readings were shown in Table 4.

Accuracy: Recovery experiments were performed to determine the accuracy of the proposed procedure by applying varying concentrations (80 %, 100 %and 120 %) of bulk samples of TROS within the linearity range and adding 10mg/ml to the pre-analyzed concentration formulation [9]. From that % recovery values were calculated. The results were shown in Table 5.

Table 3: Amount of Trospium chloride in formulation by proposed method.

S.No	Formulation	Drug	Labeled amount(mg)	Observed amount	%Recovery
1	Rospium ROS-XR	Trospium chloride	60	57.7±0.242487	96.1%

Table 4: Precision data

S.NO	Concentration(ug/ml)	AbsorbanceAt 280nm
1	30	0.163
2	30	0.162
3	30	0.163
4	30	0.161
5	30	0.162
6	30	0.162
Mean		0.1621
S. D		0.000753
%R.S. D		0.464

Table 5: Accuracy data

80%						
S.No	Conc(bulk)	Conc(formln)	%Recovery	Mean	S. D	%R.S. D
1	8	10	111.7	103.9%	9.98	0.0094
2	8	10	94.4			
3	8	10	111.7			
100%						
4	10	10	92	92.1	0.288	0.3132
5	10	10	92.5			
6	10	10	92			
120%						
7	12	10	96.8	96.9%	0.2309	0.238
8	12	10	97.2			
9	12	10	96.8			

Summary

Pharmaceutical research basically means that pharmaceuticals are analysed. Today, pharmaceutical research requires much more than an analysis of active pharmaceutical ingredients or a manufactured substance. The pharmaceutical industry is subject to heightened government and public stakeholder oversight to reduce costs and to reliably bring healthy, efficient drugs to the consumer that address unmet patient needs. In maintaining the origin, safety, effectiveness, purity, and consistency of a drug product, the pharmaceutical analyst plays a significant role [10]. The need for pharmaceutical analysis is primarily motivated by regulatory specifications. In general, the widely used pharmaceutical research tests include the development of compendia testing system, establishing criteria and evaluation of methods. One of the most interesting ways for scientists to take part in the quality process is by empirical research, which offers real evidence on the identification, substance and purity of drug products. With a great deal of commitment to global harmonization, new approaches are now being developed. As a consequence, it is possible to ensure that emerging goods have similar consistency and can be taken more easily to foreign markets.

Pharmaceutical research plays a pivotal role in the statutory approval, either by industry or by regulatory bodies, of medicines and their formulations. In industry, the divisions of quality assurance and quality management play a significant role in delivering a safe and reliable type of prescription or dose. The latest Good Manufacturing Practices and the recommendations of the Food Drug Administration (FDA) insist that sound analytical methods with greater specificity and reproducibility be followed. The sophistication of the problems encountered in pharmaceutical research is therefore critical for achieving the selectivity, speed, low cost, simplicity, specificity, sensitivity, accuracy and precision of drug estimation.

Conclusion

The method proposed was simple, sensitive and accurate with good precision and accuracy. The proposed approach is precise when calculating commercial formulations without intervention from excipients and other additives. This approach can also be used for the regular assessment of TROS in bulk samples and pharmaceutical formulations.

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