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Ultraviolet Spectrophotometric Determination of Trifluoperazine. HCl in Pharmaceutical Preparations and Environmental Wastewater Samples: Application to Content Uniformity Testing.

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Research Article

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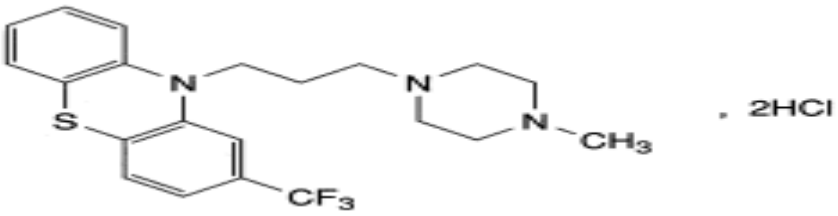
ABSTRACT

A simple, accurate, precise, rapid, economical and sensitive UV spectrophotometric method has been developed for the determination of trifluoperazine Hydrochloride in pharmaceutical preparations and environmental wastewater samples, which shows maximum absorbance at 257 nm in distilled water. Beer's law was obeyed in the range of 10 - 100 µg/ ml ,with molar absorptive of 5.284×10^3 $L.mol^{-1}.cm^{-1}$, relative standard deviation of the method was less than 1.6%, and accuracy (average recovery %) was 100 ± 1.2 . No interference was observed from common excipients and additives often accompany with trifluoperazine Hydrochloride in pharmaceutical preparations .The method was successfully applied to the determination of trifluoperazine Hydrochloride in some pharmaceutical formulations (tablets) and industrial wastewater samples. The proposed method was validated by sensitivity and precision which proves suitability for the routine analysis of trifluoperazine Hydrochloride in true samples.

INTRODUCTION

Trifluoperazine Hydrochloride,(Stelazine), chemically , 10-[3-(4-methylpiperazin-1-yl) propyl]-2 tirfluoro methyl phenothiazine dihydrochloride(Figure 1), is a derivative of phenothiazine [1].



$C_{21}H_{24}F_3N_3S,2HCl$ 480.4

Figure 1: Trifluoperazine Hydrochloride Chemical structure of

Cream coloured fine powder from absolute alcohol, freely soluble in water, insoluble in dilute base, ether and benzene[2]. Trifluoperazine is a typical anti-psychotic drug of the phenothiazine group. It has a central anti-adrenergic, anti-dopaminergic and minimal anti-cholinergic activity. It mainly acts on dopamine receptor. The primary indication of trifluoperazine is schizophrenia. Trifluoperazine HCl is effective for the short-term treatment of generalized non-psychotic anxiety[1]. The literature survey reveals that various methods has been reported for estimation of some anti-psychotic drug by Indirect Titrimetric[3]. Spectrofluorometric [4-6] Spectrophotometric [7-12], RP-HPLC[13-17], LC [18] and Indirect Atomic Absorption Spectrometric [19] . In the view of the need in the industry for routine analysis of trifluoperazine, attempts are being made to develop simple and accurate instrumental methods for quantitative estimation of trifluoperazine. Thus there is need for the development of new, simple, sensitive and

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accurate analytical method for the quantitative estimation of trifluoperazine as an active pharmaceutical ingredient. The present work describes simple and accurate Spectrophotometric methods for the estimation of trifluoperazine hydrochloride in bulk , dosage form and environmental wastewater samples.

EXPERIMENTAL

Apparatus

Shimadzu UV- 1700 pharmaspec (double beam) spectrophotometer with 1.0 cm quartz cells was used for absorption measurement.

Reagents

All chemical used were of analytical or pharmaceutical grade and trifluoperazine standard material was provided from AL-hokamaa company for pharmaceutical industries (HPI) Mosul-Iraq.

Trifluoperazine hydrochloride stock solution (1000 ppm) was prepared by dissolving 0.1g of trifluoperazine hydrochloride in 100 ml distilled water in a volumetric flask.

Trifluoperazine hydrochloride standard solution (100 ppm) was prepared by diluting 10 ml of stock solution to 100 ml by distilled water in a volumetric flask.

Determination of absorption maxima

The standard solution of trifluoperazine Hydrochloride (60µg/ml) was scanned in the range of 220-350 nm which shows maxima located at 257 nm Fig 2. Therefore ,257 nm wavelength was selected for the construction of calibration curve.

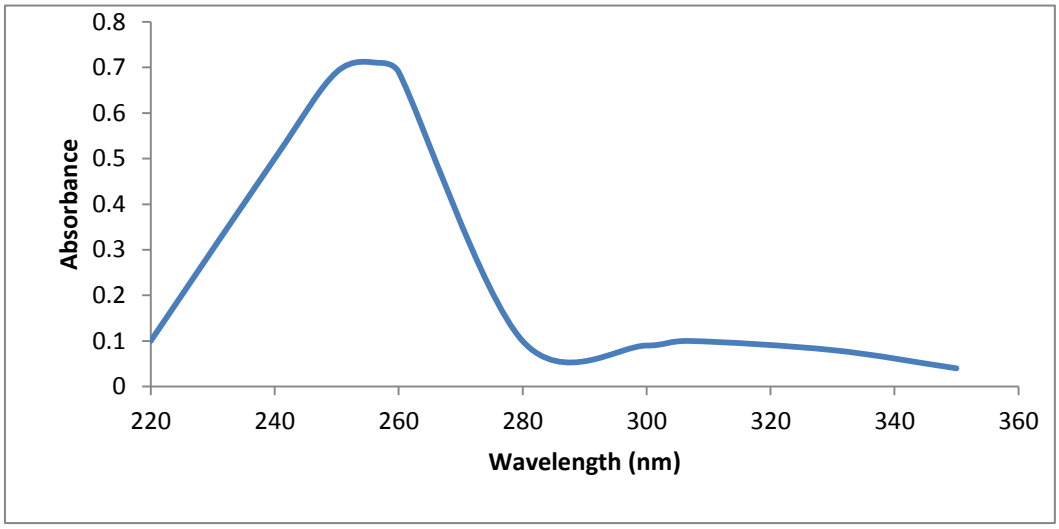

Figure 2:-Absorption spectra of 60 (µg/ml) trifluoperazine Hydrochloride against distilled water.

Recommended procedure

From the absorption maxima ,calibration curve was prepared in the concentration range of 10-100 µg/ml . The absorbance was measured at 257 nm against distilled water as a blank .The concentration of the sample solution can be determined by using the calibration curve.

Procedure for real water samples

To demonstrate the practical applicability of the proposed method, real water samples were analyzed by this method. Industrial waste water from AL-hokamaa company for pharmaceutical industries (HPI) Mosul-Iraq , were fortified with the concentrations in the range of 20,30,60 µg/ml of trifluoperazine Hydrochloride. The fortified water samples were analyzed as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

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Procedure for pharmaceutical preparations (tablets)

Weight and powder 10 tablets . Dissolve a quantity of the powdered tablets containing 0.01 gm of trifluoperazine hydrochloride in about 100 ml distilled water and mixed for 20 mint and then filtered. The filtrate was mad up to 100 ml with distilled water and aliquot of this solution was treated as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

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RESULT AND DISCUSSION

UV- Visible spectrophotometry is still considered to be a convenient and low cost method for the determination of pharmaceuticals. The method used for the determination of trifluoperazine Hydrochloride in pharmaceutical preparations and environmental wastewater samples was found to be sensitive ,simple ,accurate ,and reproducible .Beer s law was obeyed in the concentration range of 10-100 µg/ml Fig 3 with correlation coefficient of 0.998 ,intercept of 0.003 and slope of 0.011 .The conditional molar absorptive was found to be 5.284 x10^3 l/mol.cm.

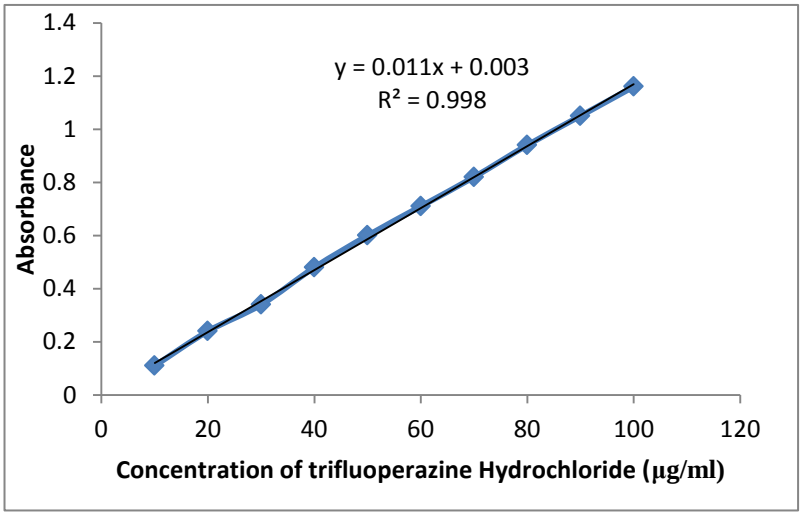

Figure 3:Calibration curve for trifluoperazine Hydrochloride.

The accuracy and precision of the method ,a pure drug solution was analyzed at three different concentrations ,each determination being repeated six times. The relative error(%) and relative standard deviation values are summarized in table 1.From table 1 the values of standard deviation were satisfactory and the recovery studies were close to 100%,.The RSD% value is less than1.6 indicative of accuracy of the method.

Table 1: Accuracy and precision of the proposed method.

Trifluoperazine Hydrochloride taken(µg/ml)	Er (%)[a]	RSD(%)
20	1.1	1.4
30	1.1	1.5
60	1.2	1.5

[a] Mean of six determinations.

The proposed method was compared with other reported UV-Spectrophotometric methods and found to be superior (Table 2).

Table 2: Comparison of the existing UV-Spectrophotometric methods with the proposed method for trifluoperazine Hydrochloride.

Parameters	Method 1	Method 2	Method 3	Method 4
Ref	**7**	11	12	Proposed
λMax(nm)	**2**55.5	265	269	**257**
Solvents	0.1N HCl	Methanol	H_2O	H_2O
Linear range µg/ml	2-35	2- 45	5-35	10-100
ε(l/mol.cm)	3.027x10^4	2.049x10^4	4.332 x10^3	5.284 x10^3
RSD%	Less than 2	Less than 1	0.764	Less than 1.6
Application	pharmaceutical preparations	pharmaceutical preparations	pharmaceutical preparations	Pharmaceutical preparations and industrial wastewater

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Analytical application

The proposed method was satisfactorily applied to the determination of trifluoperazine Hydrochloride in its pharmaceutical preparations tablets and wastewater samples ,the results of the assay of the pharmaceutical preparations revels that there is close agreement between the results obtained by the proposed method and the label claim Table 3,and the results of water samples Table 4 show that the recovery values obtained were closed to 100% .

Table 3: Assay of trifluoperazine Hydrochloride in pharmaceutical formulations.

Pharmaceutical formulation supplied by HPI	Amount of trifluoperazine Hydrochloride *	Label claim	%Recovery
Tablet 1mg	1.008mg	1 mg	100.8

*Mean of ten determinations.

Table 4: Determination of trifluoperazine Hydrochloride in spiked industrial wastewater sample.

Water samples	Trifluoperazine (µg/ml) *		%Recovery
	Taken	Found	
Industrial wastewater	20	20.04	100.2
	30	29.92	99.73
	60	59.89	99.81

*Mean of ten determinations.

Application of the method to content uniformity

The proposed method proved to be suitable for the content uniformity test, where a great number of assays on individual tablets are required. Data presented in Table[5] indicate that the proposed method can accurately and precisely quantitate trifluoperazine Hydrochloride in its commercially available tablets. The mean percentage (with RSD) of the labeled claim found in ten tablets was (0.518%) which fall within the content uniformity limits specified by the USP 30 [23].

Table 5: Content uniformity testing of trifluoperazine Hydrochloride tablets using the proposed method

Parameter	% of the label claim
Tablet NO. 1	100. 28
Tablet NO. 2	100. 11
Tablet NO. 3	99. 56
Tablet NO. 4	100.71
Tablet NO. 5	99.38
Tablet NO. 6	99. 35
Tablet NO. 7	99.72
Tablet NO. 8	100. 55
Tablet NO. 9	100.66
Tablet NO. 10	99.76
Mean ($\bar{x}$)	100.008
% RSD	0.518
Max. allowed unit (23)	±15%

CONCLUSION

In this work, a simple, rapid, precise and accurate UV-Spectrophotometric method was developed and validated for the determination of trifluoperazine Hydrochloride in pharmaceutical preparations and industrial waste water samples. The method free from such experimental variables as heating or solvent extraction steps. The method rely on the use of simple and cheap chemicals and techniques and can be used for rapid routine determination and quality control of trifluoperazine Hydrochloride in pure form, pharmaceutical preparations and real industrial waste water sample.

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