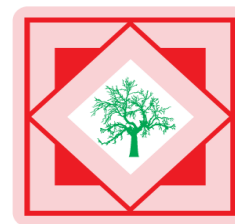




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Spectrophotometric determination of tramadol hydrochloride and diclofenac sodium in pharmaceuticals and environmental samples

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ABSTRACT

Direct spectrophotometric determination of tramadol hydrochloride (TH) and diclofenac sodium (DS) in water samples has been examined. The effect of presence of some common ions on the absorbance of tramadol hydrochloride and diclofenac sodium has been also tested, and real water samples and tramadol tablets have been analyzed.

Keywords: Tramadol, Diclofenac, Environmental water sample, spectrophotometry.

INTRODUCTION

The increasing availability and affordability of medical treatment in many countries, has led to an increased production and consumption of different classes of pharmaceuticals, both those that require a prescription and those that do not.

In recent years, a number of pharmaceuticals have been reported to be potentially toxic substances often found rather widely in the environment. Hundreds of pharmaceutical substances of differing therapeutic class, together with their metabolic by-products, have been detected in different environmental matrices these threatening the health of many sensitive living organisms including, including human.[1-4]

The most common methods for determination of pharmaceuticals in the environment are gas chromatography or liquid chromatography. Therefore there is need for a simple and direct method applicable for this purpose specially in the developed countries.

Tramadol hydrochloride¹ (TH) [figure (1)] is a monoamine uptake inhibitor and centrally acting analgesic, used for treating moderate to severe pain. Tramadol hydrochloride is chemical (+/-) cis-2- (Dimethylamino) methyl)-1-(3-methoxy phenyl cyclohexanolhydrochloride.[5]

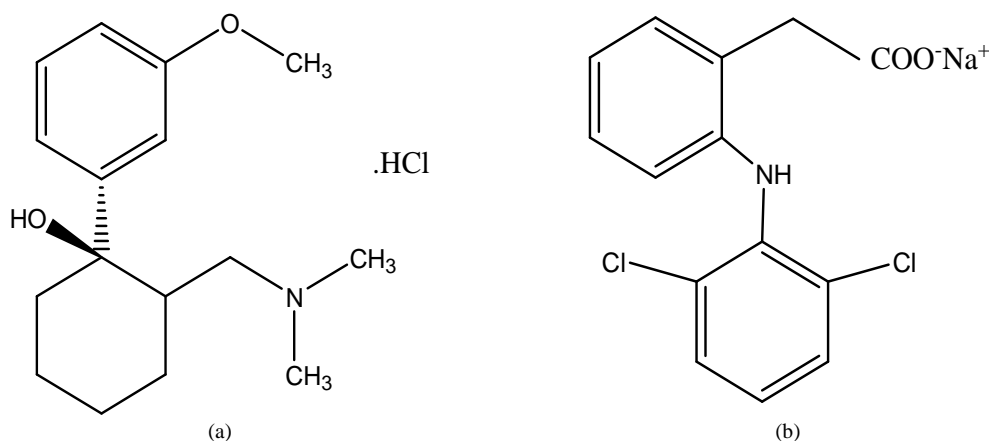


Figure (1): Structure of (a) Tramadol Hydrochloride, (b) Diclofenac Sodium

Spectrophotometric method provides sensitivity, precision and accuracy of analysis, thus it offers practical and economical advantages over other techniques. There are methodologies developed for the spectrophotometric determination of tramadol in many types of samples.

Diclofenac sodium is used as an Analgesic; anti-inflammatory. Chemically Diclofenac sodium is known sodium 2-[(2,6-dichlorophenyl)amino]phenyl]acetate.[6]

It is a broadly used non-steroidal anti-inflammatory drug [7] for the treatment of inflammatory conditions such as rheumatoid arthritis, osteoarthritis and ankylosing spondylitis [8]. Different analytical methods have been employed for the quantification of DS, such as spectrophotometry [2,9], fluorimetry [10,11], FT-Raman spectroscopy [12,13], potentiometry [6], chromatography [3,14], voltammetry [15], and polarography [16]. Most of these methods face certain problems such as the use of additional reagents, complex formation, long time and hazardous matrices. In contrast simplicity, economy, green chemistry and faster assay are the actual factors which make a method far more superior to those lacking one or more of these characteristics.[17]

Abdul Rauf Khaskheli, et. al. described a simple, sensitive, rapid and economical analytical procedure for direct spectrophotometric evaluation of diclofenac sodium (DS) using aqueous medium without using a chemical reagent. Parameters like time, temperature, acidic and basic conditions and interference by analgesic drugs were studied for a 5µg ml⁻¹ solution of DS at 276 nm.[17] This method has been used in our study for determination of diclofenac sodium in some pharmaceuticals and water samples. The ability to use the method in determination of DS in water samples has been tested.

In this work, direct UV spectrophotometric determination of tarmadol has been investigated and the optimum conditions were studied.

MATERIALS AND METHODS

CECIL – CE 7400 (Aquarius), UV-Visible spectrophotometer, Double beam with quartz 1.000 cm path cuvettes was used to perform analyses.

All reagents were of analytical grade. excepting diclofenac sodium (Refen – made in sirdia) and tramadol (Mabron – Limassol, made in Cyprus) that were pharmaceutical certificated solution products. Tramadol tablets were purchased from the local market (Tramadol-X 225, singh-nature).

RESULTS AND DISCUSSION

Finding lambda max (λ_{max})

The maximum absorbance were at 270.2 and 275.3nm for TH and DS respectively. For tramadol, UV spectra were recorded at 270.2 nm for standard solutions of TH with different concentrations in the range of 0–40 µg ml⁻¹, Linear equation obtained from calibration plot is represented as; $y = 0.006x + 0.014$ with regression coefficient of $R^2 = 0.995$. In case of diclofenac sodium, UV spectra were recorded at 275.3 nm for standard solutions of DS with different concentrations in the range of 5–30 µg ml⁻¹ Linear equation obtained from calibration plot is represented as; $y = 0.0331x + 0.0435$ with regression coefficient of $R^2 = 0.9982$.

Effect of pH

Eight aliquots of 20mg/L of TM covered a pH range from 3-9.35 have been prepared. HNO₃ and NaOH were used to adjust the pH.

The effect of pH value on the absorbance of TH is shown in figure (2). There was no significant change in the absorbance of TH, therefore, no more additions were needed to control the pH.

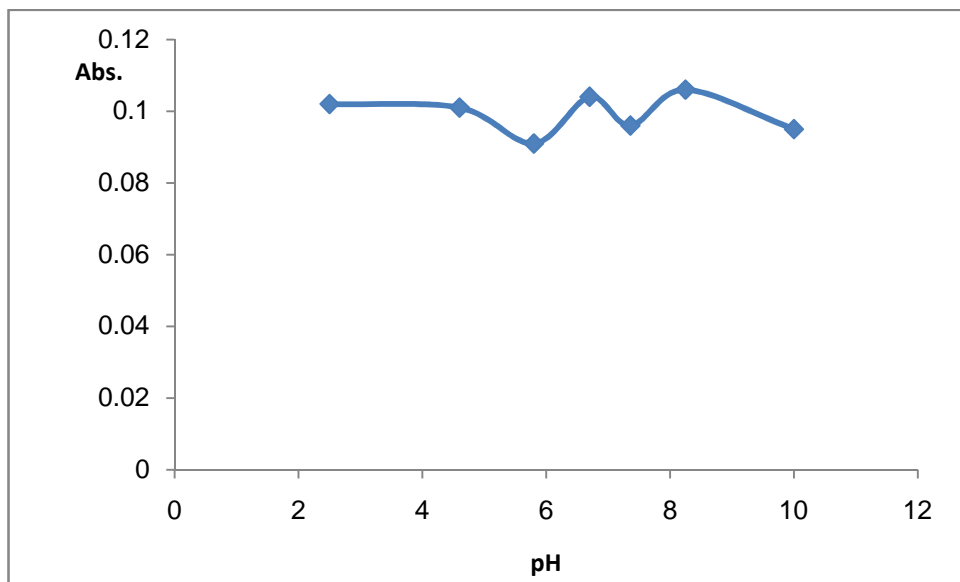


Figure (2): Effect of pH on the absorbance of Tramadol hydrochloride

Effect of temperature

The effect of temperature on absorbance of 20 μ g ml⁻¹ TH at 270.2 nm was observed in the range of 10- 45 °C. It can be seen in figure (3) that, lower temperature range of 15–25 °C shows maximum absorbance, with a little bit decreased value from 25°C followed by a further stability thereafter.

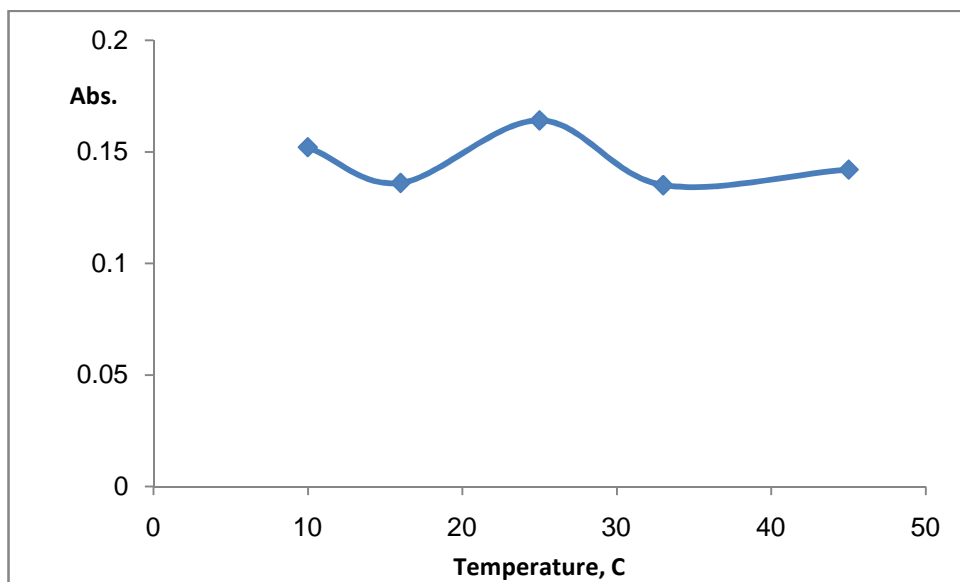


Figure (3): Effect of temperature on the absorbance of TH

The room temperature (20 \pm 5C) was taken as optimum temperature in order to make the process simple by avoiding additional steps.

Influence of time

The effect of time on the absorbance behavior of 20 $\mu\text{g ml}^{-1}$ aqueous solution of TH at 270.2 nm was studied in the range of 1–60 minutes at room temperature of $25 \pm 5^\circ\text{C}$ using distilled water as a blank solution. The absorbance was stable in this time interval (figure (4)).

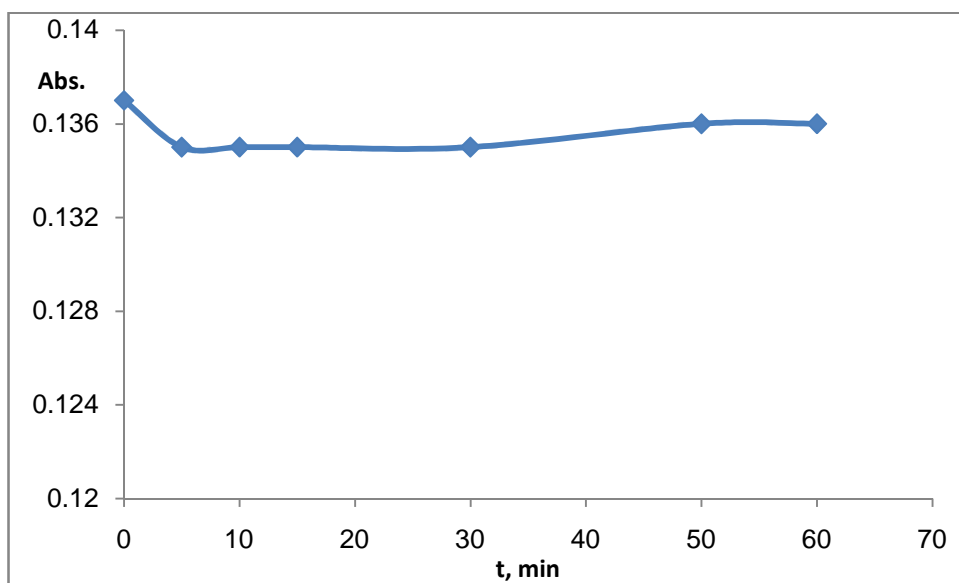


Figure (4): Effect of time on TH absorbance

Effect of some common excipients on TH absorbance

The effect of glucose, sucrose, and starch on the absorbance of TH (20ppm) has been studied in presence of different ratios of glucose, sucrose, and starch. The results are shown in figure (5). There are no significant changes observed in the absorbance of TH solution in the presence of those excipients.

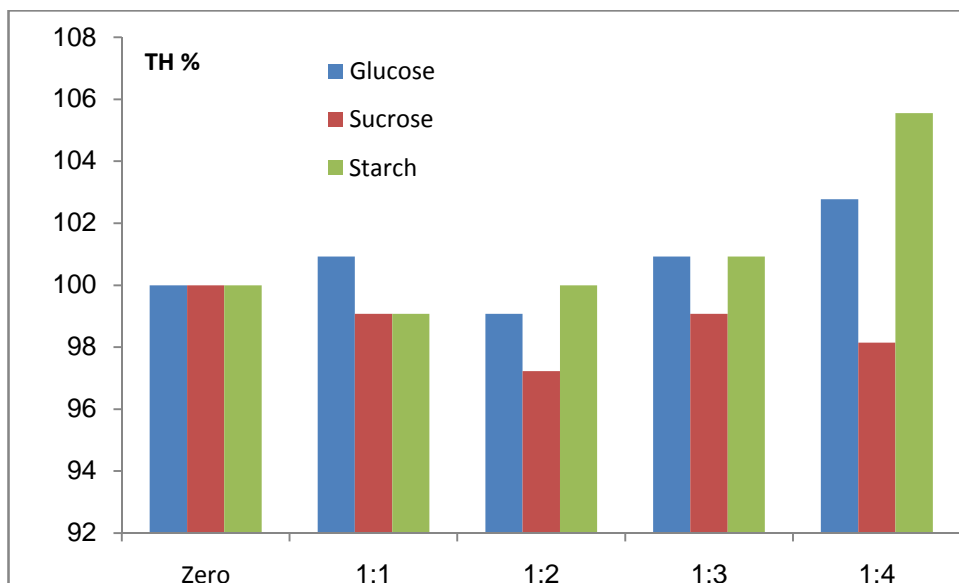


Figure (5): Effect of presence of some common excipients on the absorbance of TH

Effect of presence of some ions on TH absorbance

An aliquots of 20 mg/L of TH, and 10 mg/L for DS, have been spiked with different amounts (1:1, 1:2, and 1:4, and 1:8 in case of DS) of Ca^{2+} , Mg^{2+} , HCO_3^- , CO_3^{2-} , Cl^- , and SO_4^{2-} . The absorbance of each aliquot has been recorded against distilled water.

The results obtained are shown in figure (6). There was no significant change on the absorbance of TH in all ratios of the tested ions.

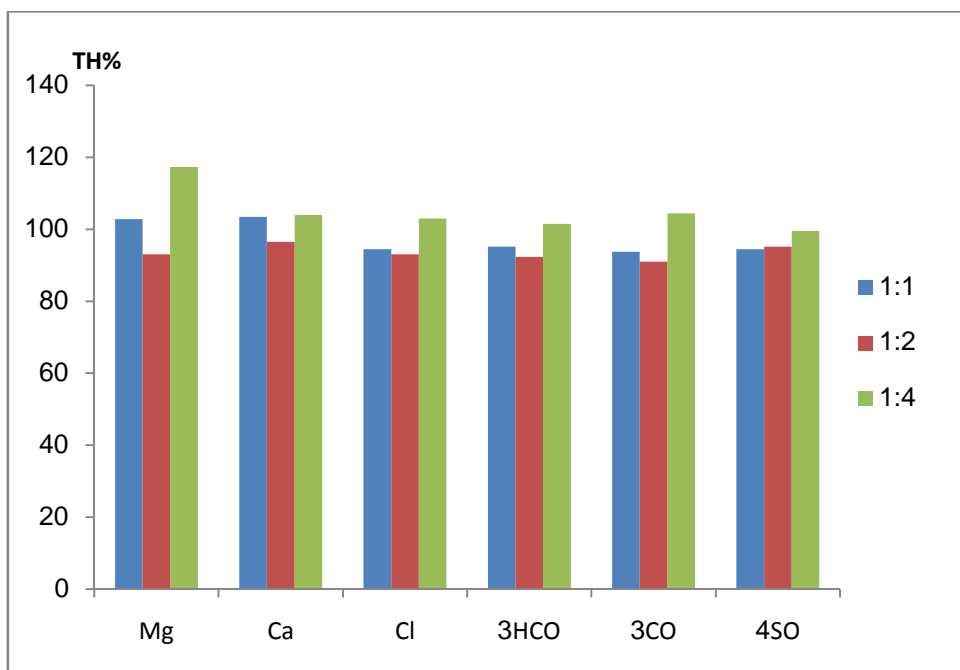


Figure (6): Effect of presence of some ions on TH absorbance

The effect of some foreign ions on the absorbance of DS is shown in figure (7).

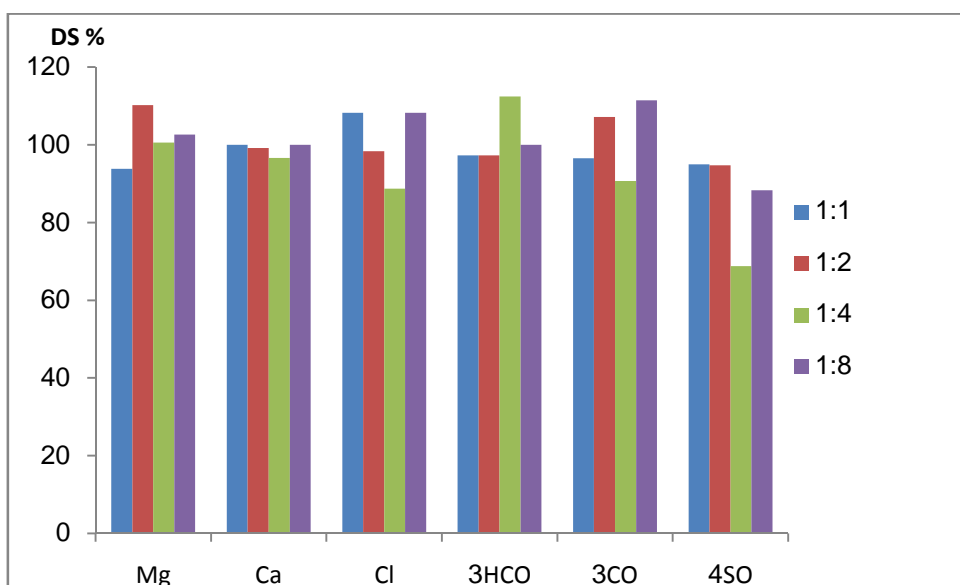


Figure (7): Effect of foreign ion presence on the absorbance of diclofenac

There was no significant change on the absorbance of DS in all ratios of the tested ions. These ions have been selected as they are the most present ions in water bodies in order to know how to proceed with real water samples. Since we are measuring the DS in ionized acetate form, it was noted that the presence of Mg^{2+} and Ca^{2+} enhance the absorption of DS, this may be according to complex formation in solution (Figure (8)).[19]

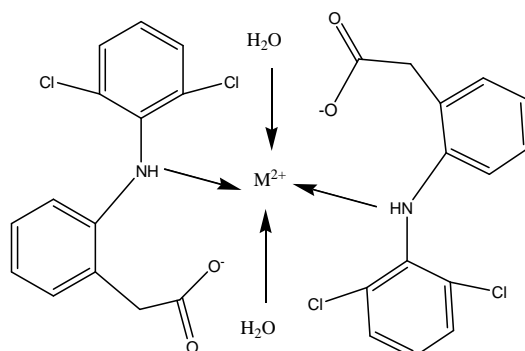


Figure (8): Metal complex with DS

Diclofenac ion acts as a "complexing agent" for the metal cation. In this form DS is a bidentate ligand; the acid oxygen and the amine nitrogen can donate one electron pair to the metal. The metal ion is held in a one-to-two complex with the DS molecule.

Determination of TH and DS in different water sample

Two types of water samples, Tap and sea water have been spiked with different amounts (0, 250, and 500 μg) of TH and (0 and 250) in case of DS. The absorbance of each aliquot has been recorded against distilled water, and the amounts of TH and DS have been calculated using the equation extracted from the calibration curve.

The results are listed in table (1) and table (2) for TH and DS respectively.

Table (1) Analysis of TH in water samples

Sample	Amount of TH added (μg).		
	Zero	250	500
Sea Water	N. D.	235.13	469.36
Tap Water	N. D.	244.14	458.10

N. D. = not detected

Table (2): Analysis of DS in water samples

Sample	Amount of DS added (μg).	
	Zero	250
Sea Water	N. D.	260.39
Tap Water	N. D.	247.01

N. D. = not detected

Determination of TH in tablets

Three tablets of commercial Tramadol hydrochloride were dissolved in 100 ml distilled water and measured after the proper dilution to be in the linear calibration curve. The amount found was 234.38 mg/tablet. The amount stated on the package was 225 mg/tablet.

CONCLUSION

Direct determination of tramadol hydrochloride and diclofenac sodium in tablets and water samples can be performed. This method can be used in monitoring of sea coast areas which in contact with waste water plants effluent.

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