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Measuring the Effectiveness of the Active Ingredient in the Drug Histadine by Ultraviolet Spectroscopy and Comparing the Results with Previous Studies

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ABSTRACT

An accurate, simple and sensitive spectroscopic method was developed to measure the percentage of the effect of the active substance loratadine, which is included in the compositions of most antihistamine pharmaceutical compounds, including the drug histamine, which is used to treat seasonal allergies and colds in the form of runny nose and sneezing, and also to relieve and calm the symptoms of urticaria, or what is known as skin urticaria, resulting from contact with irritating substances or exposure to different temperatures, in its pure form and in pharmaceutical preparations. ، The effectiveness of loratadine was measured by replacing the drug tablets after converting them into powder using(1)

First: Ethanol and acetone alcohol in a ratio of 1:1. The ultraviolet spectrometer recorded a decline in determining the calibration curve and the curve did not reach the zero percentage, which made it impossible to measure the effectiveness of the drug

Second: Using 100% distilled water, the pure substance was replaced, as well as in its pharmaceutical form. The device recorded a calibration curve and the percentage of loratadine effectiveness and its solubility in distilled water. The percentage ranged between 1-300 nanometers(2)

The results indicated that there were no interferences of excipients in the process of measuring the effectiveness of loratadine. The method was successfully applied to measure the dissolution rate and effectiveness of the drug compound in pharmaceutical preparations(3)

Keywords: Antihistamines, Loratadine, UV spectroscopy

Introduction:

Histidine is an alpha amino acid whose side chain is in the form of a five-membered ring, and nitrogen forms two corners of this ring. It also carries a positive electrical charge on one side of the two nitrogen atoms, so it is classified as a positively charged amino acid. Its chemical formula is(C6H9N3O2)

Its molar mass is 155.15 g.mol-1 and it plays an important role in stimulating inflammatory reactions because it produces histamine, which performs this vital function in the body (4)

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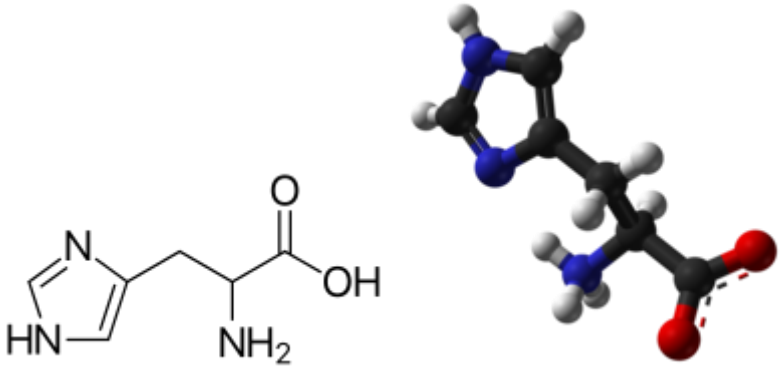

Figure No. (1): The structural formula of histidine

Histamine is a chemical found in some cells of the human body

It causes allergic symptoms. When a person is allergic to certain substances, such as food or dust, the immune system mistakenly believes that this substance is harmful to the body(5)

It starts a reaction that prompts some of the body's cells to release histamine and other chemicals into the bloodstream, causing various allergy symptoms such as a runny nose or sneezing. Antihistamine medications, including histidine, help combat these symptoms(6)

Antihistamines are divided into two main groups: the first, called the first generation, causes drowsiness, to which the drug Histadine belongs, and the second group is the second generation(7)

It does not cause drowsiness to a great extent. Antihistamines come in different pharmaceutical forms, either in pure form or in a synthetic form mixed with other substances such as paracetamol and decongestants(8)

It was noted in the literature that the amount of loratadine, the active ingredient in the composition of the drug Histadine, was measured and estimated(9)

using different spectroscopic and analytical methods, including the ultraviolet spectroscopy method, where the estimate was made at a wavelength of 275 nanometers, as well as the drug was estimated using reversible and irreversible high-performance liquid chromatography(10)

Also in electrical methods of measuring potential difference using cathodic extraction(11)

The current study aims to measure the

effectiveness of loratadine in the drug Histadine and its solubility in distilled water and compare the results with the results of other scientific studies, since loratadine is poorly soluble in water

UV-Visible Spectrometry: The UV-Visible Spectrometry method is one of the most scientific methods used in pharmaceutical analysis. Its basic operation is based on measuring the amount of ultraviolet rays, whose wavelengths range between (190-380 nanometers), or it can be measured using visible rays, whose wavelengths range between (380-800 nanometers)

And absorbed by the solution whose absorption rate is to be measured using an auxiliary substance and according to the type of drug whose spectrum

is to be estimated. The units that measure the rate, characteristics and depth of light radiation entering the measurement area are known as the ultraviolet spectrophotometer. Light absorption occurs in both the ultraviolet and visible regions of the electromagnetic spectrum

The light power required to cause a transitional motion within the solution molecules and the associated vibrations and rotational transitions is also proportional to the.

Materials and Methods

Apparatus and Methods

In this study, a UKT90 UV-visible spectrophotometer equipped with a quartz cell was used, and a KERN ABS-Germany sensor balance was used to calculate the heavy radiation quantities required to prepare the solutions, which were prepared using ethanol-acetone alcohol in a ratio of 1:1 and distilled water with hydrochloric acid at a concentration of 0.01 as a dissolving agent

In this study, pure chemicals prepared by Chemisan Company were used, as well as tablets from the General Company for the Manufacture of Medicines and Medical Supplies in Samarra, to prepare the antihistamine (Hystadine). A solution of it was prepared at a concentration of 500 mcg/ml after weighing 0.05 g of it and dissolving it in 1:1 ml of ethanol and acetone alcohol, and the second in 100% pure distilled water

. The solution of the pharmaceutical preparation Chlorphenami Maleate 4mg / Iraq containing (Histadin) was prepared by grinding 10 tablets and converting them into powder and taking a weight from it (0.375 g) equivalent to 0.03 g of the pharmaceutical compound and dissolving it in the same way followed in dissolving the standard solution. After filtering the solution, the clear solution was transferred to a 100 ml volumetric bottle to obtain a solution with a concentration of 300 mcg / ml. The solution must be prepared freshly before the measurement process is carried out.

Method used to estimate and measure the effectiveness of antihistamine (Hystadine)

At first, 0.10 ml of 300 mcg/ml of Hystadine solution was transferred to a 10-volume flask with 0.01 mcg/ml of hydrochloric acid and the solution was diluted with pure distilled water to the mark. A white solution was obtained. The solution recorded its maximum absorption at 275 nm and the recovery rate of Loratadine ranged from 99.90 to 100.50%

Results and Discussion: After following the proposed method of measuring the effectiveness of the drug in estimating the solubility of the drug (Hystadine) in pure distilled water, the resulting model solution was measured with a range of wavelengths in the visible region ranging between (200-400). An absorption spectrum appeared that gave its maximum peak at a wavelength of 275 nm. While the other solution dissolved in alcohols did not give any noticeable absorption in that region..

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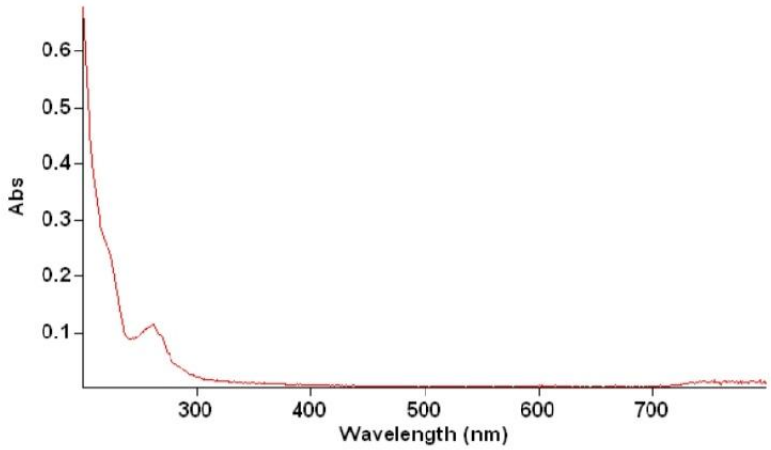

Figure 2: Final absorption spectrum to measure the effectiveness and solubility of Histadine in pure distilled water.

Optimal conditions for measurement:

The various factors affecting the measurement of the absorption capacity of the model solution between the compound antihistamine (Hystadine) at a concentration of 4 mcg/ml were studied and the coupling revealed the following:

Types of solutions that aid in dissolution: This was done by adding alcohols as a solvent that helps in dissolving the active ingredient in the composition of the drug Histadine (Loratadine) and also by adding a very dilute concentration of hydrochloric acid as an oxidation reagent with a concentration of 0.01 molar for each of (C2H6O, C3H6O and HCL). It was found that HCL of 0.01 molar was preferred and aided in absorption. However, increasing the volume of the solution more than 0.5 ml caused a decrease in absorbance by increasing the concentration from 2 to 6 mcg/ml.

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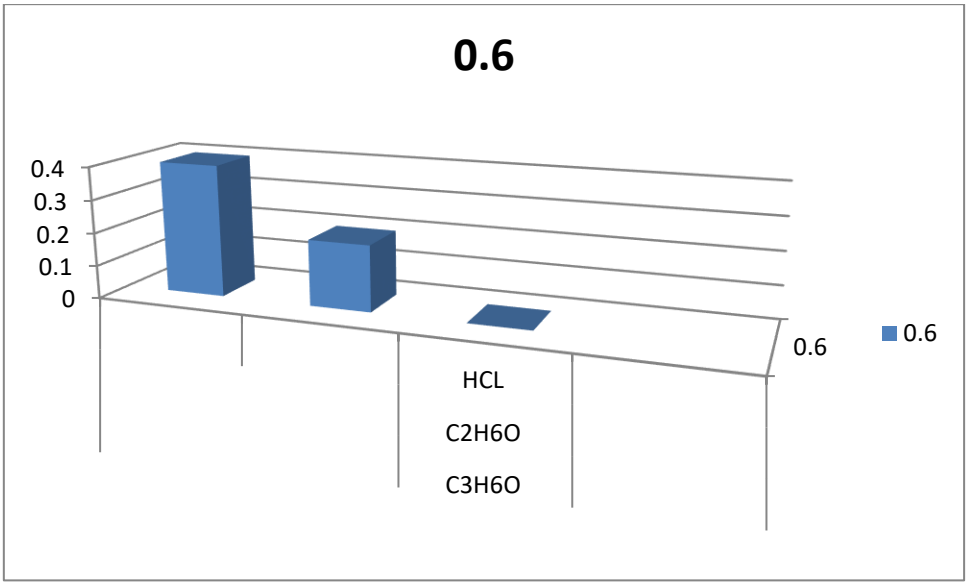

Figure No. (3)

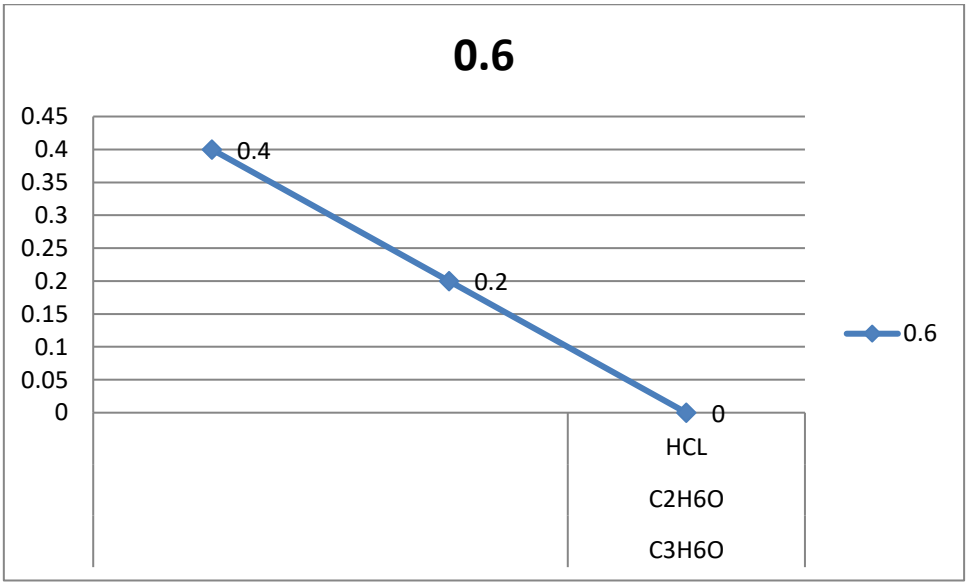

Figure No. (4)

Table No. (1)

%RSD	Standard deviation	Recovery of Hystadine	Amount of standard drug added ml
0.090	0.091186	99.00%	2
0.0442	0.044093	100.00%	4
0.2236	0.22362	98.99%	6

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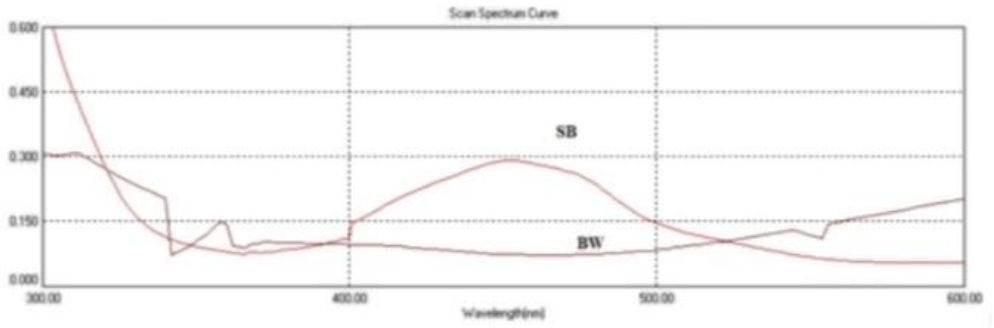
Table No. (2)

Drug	Label clam (mg)	Amount found (mg)	Purity %
Hystadine	4 mg	99.5	99.5

Conclusions:

The recovery samples confirmed that the proposed technique is valid and reproducible. The test results showed that any slight change in the drug concentration in the solution can be adequately determined with the help of the proposed technique. The accuracy and reproducibility of the proposed techniques were confirmed by the percent recovery values which were close to 100 and decreased with the decrease in the standard deviation values The results of the repetition indicated accuracy under the same operating conditions and over a short period of time and accuracy between tests. It also showed good agreement and was characterized by ease and sensitivity. It was performed in a pure aqueous medium without the need for prior treatment of the drug samples. The method did not require temperature control or the use of organic solvents because the drug has a high solubility and dissolution in distilled water...

Previous studies to estimate the drug Loratadine: - The results of this study were relied upon because Loratadine is the active ingredient in the drug Histadine, and the results were as follows: One of the previous studies published in Samarra Journal of Pure Sciences in 2024 by researcher Asmaa Ahmed Mohammed, which used ortho-phenylenediamine as an oxidative coupling reagent in the spectroscopic determination of one of the antihistamines, which is the drug loratadine, and the reaction depended on oxidative coupling with ortho-phenylenediamine in the presence of potassium iodate KIO3 in an acidic solution at a wavelength of 453 nm. The results indicated that there were no interventions of excipients in the estimation process, and the method did not require reliance on organic solvents, since the drug has a high solubility in water([12]), and there was no need to control standard temperature conditions. The method was also characterized by ease and high accuracy, as shown in the final absorption spectrum for estimating the drug (LD) in the colored solution versus the mock solution[(13)] .



Final absorption spectrum of loratadine solution

Conclusion:

The effects of the prevailing study indicated that the developed approach is simple, accurate and cost-effective, as well as the UV spectrophotometric drug efficacy measurement technique for the estimation of the efficacy of histidine for routine quality control analysis of both high and low concentrations and according to its pharmaceutical forms. The innovative and low-cost method proved to be effective, easy to handle, fast and smooth in performance

With a small pattern size of the drug, it was reproducible and could be followed to evaluate the best repeatable treatment of the UV spectrophotometric method for the drug histidine in its pharmaceutical form..

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