

Green Synthesis-Based Spectrophotometric Method for the Determination of Triprolidine HCl in Pure Form and Pharmaceutical Products Using Biogenic Silver Nanoparticle

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Abstract

The nanoparticles of metal are particularly intriguing in nanotechnology because of their distinct chemical characteristics. The purpose of this work was to develop a simple, low-toxicity, and inexpensive method to determine triprolidine hydrochloride (TRP) in pharmaceutical and pure dose forms. The current study uses an aqueous extract of *Salvia officinalis* leaves to create AgNPs in a green way. Ultraviolet-visible (UV-Vis) and infrared (IR) spectroscopic measurements were performed at the Chemistry Department, College of Science, Tikrit University, while other tests were performed in specialized laboratories in Iran between October 28, 2024, and March 5, 2025. The spectroscopic results showed that the maximum absorption of the nanoparticle-drug mixture was at 451 nm, with a strong linear relationship within the concentration range (2-28 µg/ml) and a correlation coefficient $R^2 = 0.9985$. The molar absorptivity was 1.3160×10^4 L/mol cm, and Sandell's significance was 0.02392 µg/cm². The detection limit was 0.1427 µg/mL, and the limit of quantitation was 0.4324 µg/mL. The results showed a recovery rate of 99.304%, with a relative standard deviation of 0.599% and a relative error of 0.255%. The method proved to be accurate and reliable when applied to various pharmaceutical dosage forms containing triprolidine hydrochloride.

Introduction

Nanotechnology is gaining attention because of its many uses, which may be defined as the process of manipulating a material through a number of steps to produce materials with certain desired characteristics. Typically, it involves particles with sizes ranging from 1 to 100 nm [1]. The production of nanoparticles can be done in three basic ways. Biological, chemical, and physical processes are among them [2]. Chemical techniques are the most frequent, but they offer minimal benefits. Their main shortcoming is that they are not environmentally friendly methods of synthesis. There is potential for greenness with physical means, whereas

biological methods appear to uphold the principles of green chemistry almost completely [3–5]. Green nanotechnology is currently regarded as one of the most rapidly expanding scientific topics, providing the possibility of creating low-dimensional particles in an environmentally benign manner [6]. Green synthesis outperforms physical and chemical processes because it is environmentally benign, cost-effective, easily scaled up for large-scale synthesis, quick, non-pathogenic, biocompatible, clean, less dangerous, easy to use, safe, and energy-efficient, and without require poisonous or dangerous substances or high temperatures [7]. Nanoparticles' size and structure cause them to have different chemical, physical, and biological characteristics than the same material in bulk [8]. Metal precursors are the source of metal nanoparticles, which are then stabilized by a variety of organic compounds, including stabilizers and binders [9]. Silver nanoparticle production from plant extracts is currently gaining popularity due to its environmentally beneficial properties. In the creation of nanoparticles, the plant extract serves as both a reducing and capping agent [10]. Medicinal plants and their parts include a variety of useful ingredients, including bioactive chemicals. These therapeutic plants are strong in alkaloids and phenols. Plants with biologically active chemicals may accelerate the conversion of metal ions into biologically active nanoparticles in an ecologically acceptable conventional biosynthetic pathway [11]. As a result, costs and chemical agents are decreased, and the oxidation and agglomeration of metal nanoparticles that are created are also decreased [12]. Ag NPs are the most commonly used metallic nanoparticles in industries like textile coatings, biomedicine, agriculture, healthcare, and environmental protection. Comparing these nanoparticles to other kinds, they have shown remarkable antifungal, antioxidant, and antibacterial properties [13]. Triprolidine hydrochloride is a very strong antihistaminic that is used to treat a number of allergy diseases [14]. Triprolidine hydrochloride is a white, crystalline powder that has a mildly disagreeable smell. [15].

Triprolidine hydrochloride is [(E)-2-[3-(1-pyrrolidiny)-1-p-tolylpropenyl]pyridin hydrochloride].

Its chemical structure:

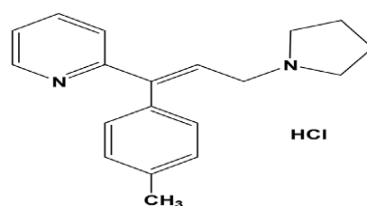


Figure 1: *The chemical structure of triprolidine HCl*

Its molecular formula is $C_{19}H_{22}N_2 \cdot HCl$, and its molecular weight is 314.85 [15]. An alkylamine derivative called triprolidine hydrochloride has modest sedative and antimuscarinic properties and is a sedative antihistamine. It is applied to pruritic skin problems and to alleviate the symptoms of allergic conditions such as rhinitis and urticaria [16]. The most frequent adverse effects include nausea, vomiting, gastrointestinal disorders, drowsiness, disorientation, incoordination, diarrhea or constipation, and epigastric discomfort [17]. Triprolidine hydrochloride has been determined using a variety of analytical techniques. Among these investigations are UV spectroscopy and visible spectroscopy, electroanalytical techniques, chemiluminescence method in conjunction with flow injection analysis (FIA), chromatography of high-performance liquids (HPLC), and chromatography by thin-layer (TLC) and others [18].

Traditional methods for the estimation of triprolidine hydrochloride suffer from some limitations, such as complexity and the use of harmful chemicals, while the analytical applications of nanoparticles prepared using green methods remain limited. In this study, silver nanoparticles were prepared using sage leaf extract and used as a novel nanoreagent to develop a simple, sensitive, and environmentally friendly method for the estimation of triprolidine hydrochloride.

Materials and methods

Tools and devices

It is used Shimadzu spectrophotometer UV-1800 (Japan), Jenway hot plate with magnetic stirrer (Germany), Sartorius BL210 S AG GOTTINGEN, EUTECH INSTRUMENTS pH 700, and Sartorius BL210 S AG GOTTINGEN.

Chemicals and drug

Tripolidine from Samarra Pharmaceutical Industries (SDI), the pharmaceutical preparation (Actifeen-1.25mg per syrup) manufactured by ASWAR AL-KHALEEJ COMPANY, Samarra, Iraq. The pharmaceutical preparation (Kindifed—2.5 mg per tablet) manufactured by AL-KINDI for pharmaceutical Ind/Baghdad/Iraq, Silver nitrate (AgNO_3), *hydrochloride* (HCl), magnesium stearate, methyl cellulose, glucose, maltose, TiO_2 , cross-carmellose, and distilled water were manufactured in the Analytical Chemistry Laboratory at the College of Science, Tikrit University.

2-3 Preparation of salvia officinalis extract

In an electric mill, the dried plant material was ground into a fine powder. After mixing 150 mL of purified water containing 10 grams of powder, the mixture was heated to 80°C for 30 minutes while being agitated. A filter paper was used to filter the extract. During the manufacture of silver nanoparticles, the supernatant was kept at 4°C as a stabilizing and reducing agent for later usage[19].

2-4 Synthesis of AgNPs using salvia officinalis extract

Silver nanoparticles (AgNPs) were made by adding 10 mL of extract dropwise to 90 mL of an aqueous solution containing 1 mM silver nitrate (AgNO_3) while stirring continuously for 60 minutes at 70°C with a magnetic heating stirrer. The reaction mixture gradually turned from light yellow to reddish brown throughout the course of the synthesis due to Localized plasmon resonance (SPR) stimulation, signifying. The existence of nanoparticles of silver and the biological reduction of Ag^+/Ag^0 utilizing plant extract [20, 21]. As shown in Figure 2.

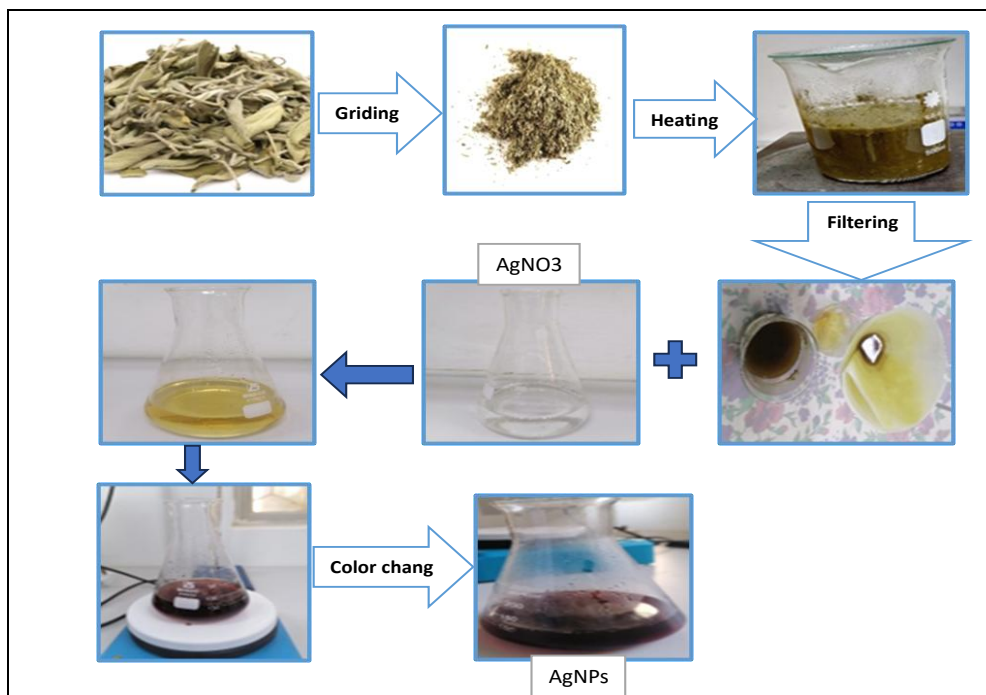


Fig.: *Synthesis of silver nanoparticles*

Preparation of Triprolidine Hydrochloride Standard Solution

The solution was prepared by dissolving 0.010 g of pure TRP (from SDI/Iraq) in an appropriate amount of distilled water with continuous stirring until completely dissolved. The solution was then transferred to a 100 mL volumetric flask and diluted to the mark with distilled water. Other concentrations were prepared by suitable dilution.

Preparation of pharmaceutical solutions

1-A solution of Actifeen® syrup (manufactured by Aswar Alkhaleej Pharmaceutical Industries / Iraq) was prepared by transferring 40 mL of the syrup (total volume 100 mL, with each 5 mL containing 1.25 mg of TRP) into a 100 mL volumetric flask. The volume was then completed to the mark with distilled water. Other concentrations were prepared by suitable dilution.

2- Ten Kindifed® tablets (Al-Kindi Pharmaceutical Industries/Iraq, total weight 2.5246 g) were finely ground in a porcelain mortar. A portion (1.0098 g) was dissolved in distilled water with stirring in a 20 mL beaker, transferred to a 100 mL volumetric flask, diluted to the mark with distilled water, and filtered to remove insoluble excipients. Other concentrations were prepared by suitable dilution.

3- General analytical procedure

The solution was prepared by mixing 1.5 mL of silver nanoparticles (AgNPs) solution with 1 mL of a standard triprolidine hydrochloride solution (100 µg/mL) and 1 mL of 0.1M HCl. The mixture was then diluted with distilled water to the mark in a 10 mL volumetric flask. Spectrophotometric analysis revealed that the maximum absorbance (λ max) of the solution occurred at 451 nm, as illustrated in Figure 3.

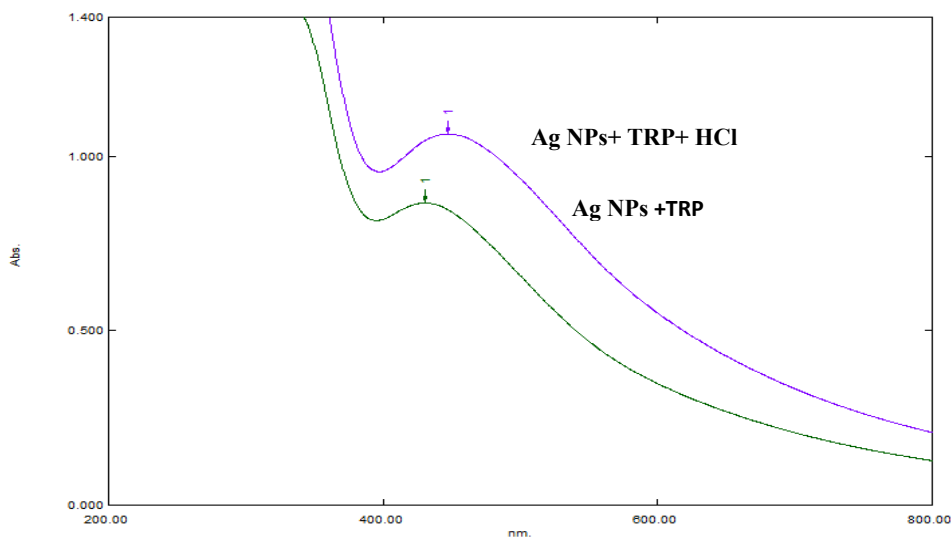


Fig 3: UV-VIS for AgNPs +TRP & AgNPs+ TRP+ HCl

Results and Discussion

The tests were conducted in a 10 mL volumetric flask containing 1mL of triprolidine-HCl at a concentration of 100µg/mL. The solution's absorbance at 451 nm was measured using 1 cm quartz cells.

Improving the conditions of the reaction

Effect of AgNPs volume

It was discovered that 2.2 mL of silver nanoparticles were convenient for the highest absorbance values for the medication, as shown in Figure 4.

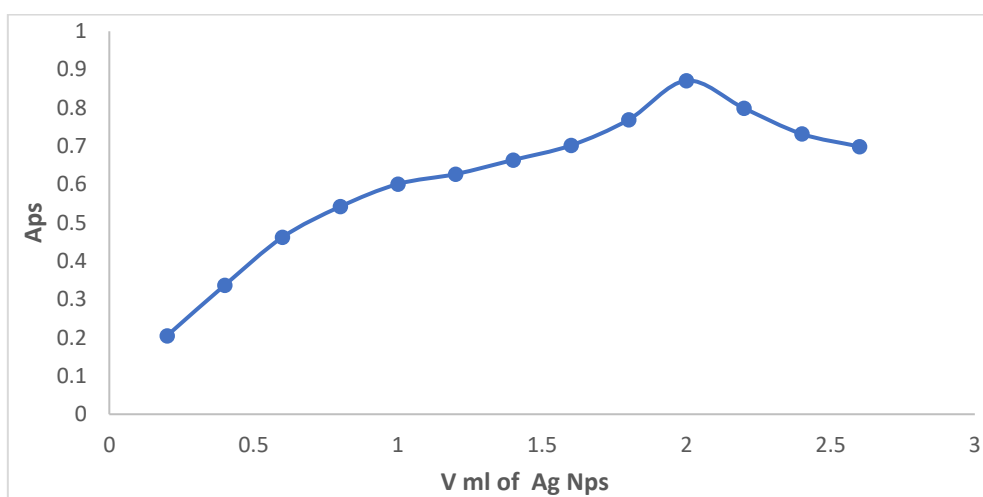


Figure 4: The optimal volume of AgNPs.

Effect of HCl volume

The maximum absorption was achieved when 1.2 mL of 0.1M HCl was added to the drug and nano-solution mixture (mix ratio 1:2.2 mL); absorption was reduced when more was added, as shown in Figure 5.

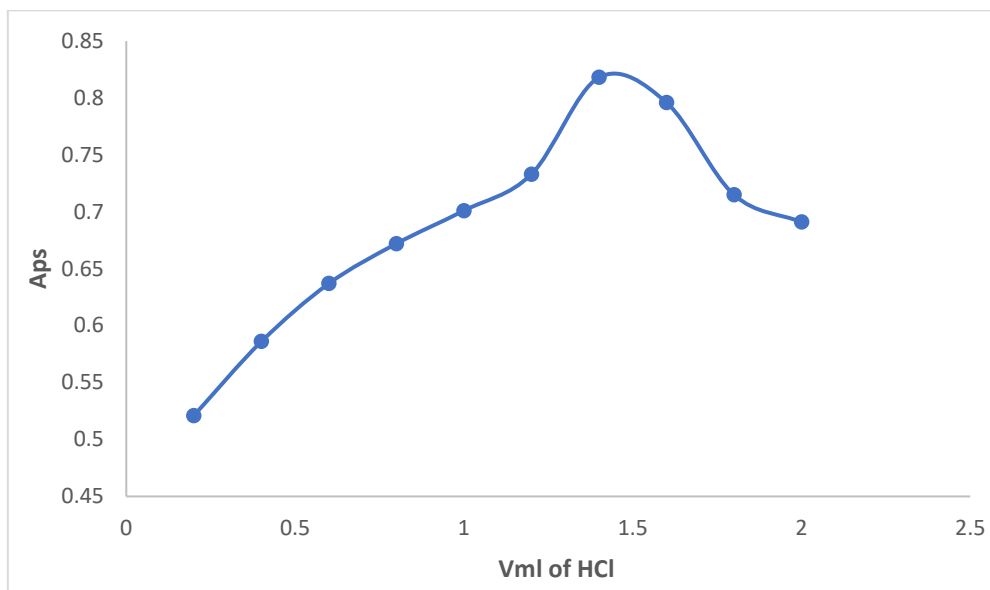


Figure 5: *The optimal volume of HCl.*

Effect of order of addition

To optimize the absorption efficiency of the produced AgNPs, the reactant addition sequence was examined, as shown in Figure 6.

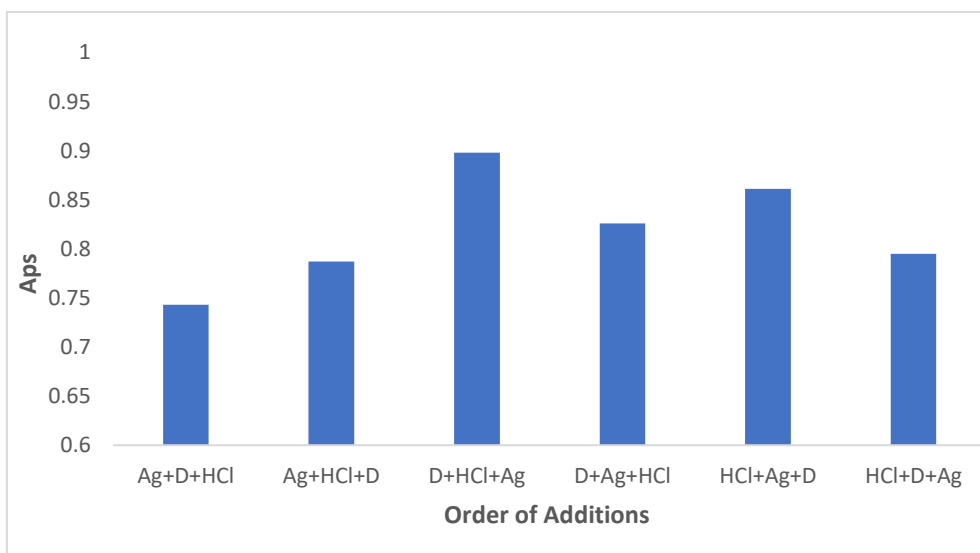


Figure 6: *Order of addition effect*

Effect of temperature

Temperatures ranging from 5 to 50°C were used to examine the effect of temperature on absorption and solution stability. The optimal temperature was discovered to be between 15 and 20°C, which was adopted in following research, as shown in Figure 7.

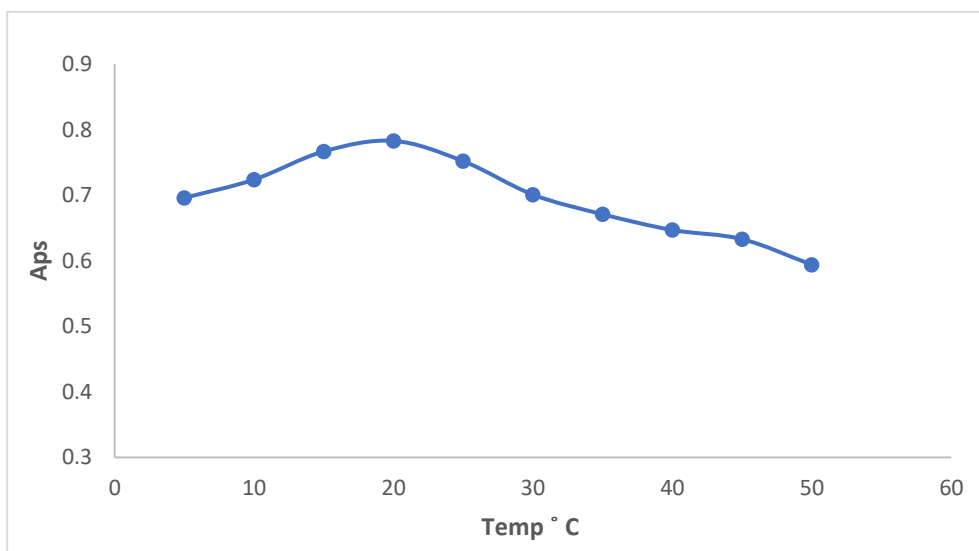


Figure 7: *Effect of temperature*

Linearity

Calibration curve

Drug dosages ranging from 2 to 26 $\mu\text{g}/\text{mL}$ were added to create a calibration curve for TRP, followed by 1.2 mL of HCl solution and 2.2 mL of AgNPs. The mixture was diluted with distilled water in a volumetric flask to a volume of 10 mL, and 451 nm was the wavelength at which the liquid absorption was measured. This was done in accordance with the defined study circumstances. Figure 8 displays the results of the calibration curve. The molar absorption coefficient was $1.3160 \times 10^4 \text{ L}/\text{mol}\cdot\text{cm}$, the correlation coefficient R^2 was equal to 0.9985, and the Sandel significance value was $0.02392 \mu\text{g}/\text{cm}^2$.

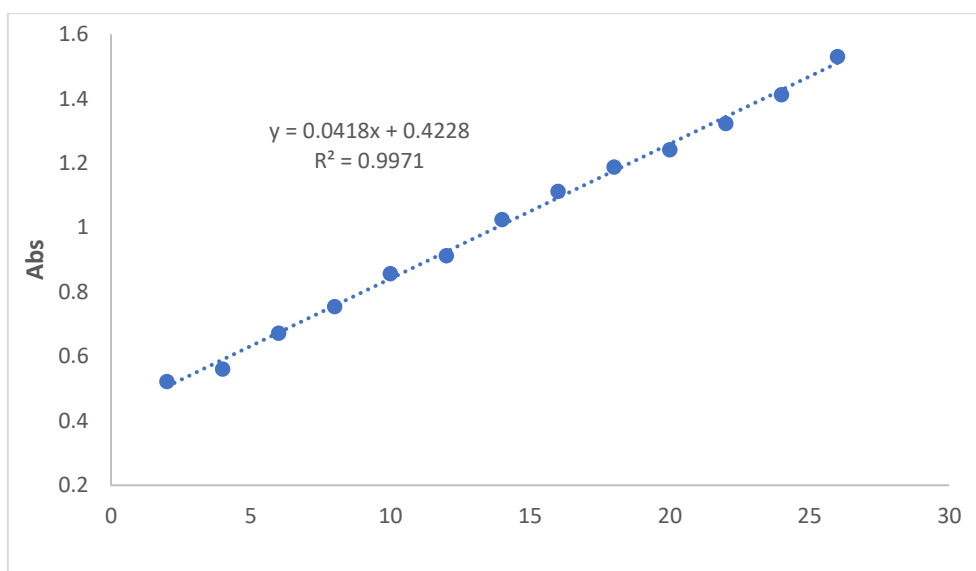


Figure 8: *Calibration curve*

Accuracy and Precision

To evaluate the clarity and correctness of the study, five distinct concentrations of (TRP) solution were sampled at the limits of the Beer-Lambert law in the calibration curve (at a rate of three readings per concentration). The recovery rate (Rec.%) and the deviation were calculated. The relative standard (RSD%) approach was found to be highly accurate and precise, as indicated in

Table 1: Accuracy and Precision

	Taken TRP $\mu\text{g}/\text{mL}$	Found TRP $\mu\text{g}/\text{mL}$	%Recovery
Pure drug	6	5.985	99.76
	8	7.875	98.44
	10	9.956	99.56
	14	13.976	99.82
	20	19.789	98.94
%Mean \pm SD		99.304 \pm 0.595	
n		5	
Variance		0.354	
%SE		0.255	
%RSD		0.599	

Sensitivity

The limits of detection and quantification (LOD and LOQ) were computed using the formulas shown below.

$$[22] \text{ LOD} = 3.3 \sigma / s \quad \text{LOQ} = 10 \sigma / s$$

The detection limit value is 0.1427 $\mu\text{g}/\text{mL}$, and the quantitative limit value (LOQ) is 0.4324 $\mu\text{g}/\text{mL}$

where S = the calibration curve's slope and σ = the standard deviation of the intersection that results from the straight-line equation's value of b . This is calculated using five calibration curve iterations.

Selectivity

The effectiveness of the suggested method's selectivity in the presence of 1 $\mu\text{g}/\text{mL}$ of TRP was assessed by testing the interfering effect of common excipients in formulations under ideal circumstances. Table 2's results indicated that TRP was not significantly interfered with; however TiO_2 and magnesium stearate did interfere with TRP somewhat.

Table 2: Analysis of the cited drug in the presence of some common excipients

Foreign Compound	%Recovery of 10 µg/mL of TRP per µg/mL foreign compound added		
	20µg/mL	40µg/mL	80µg/mL
Maltose	98.61	99.89	100.28
Glucose	97.41	98.13	99.56
Cross Caramellose	96.93	100.04	98.37
Methyl Cellulose	99.33	98.85	100.52
TiO ₂	113.205	118.708	121.1004
Magnesium striae	104.34	107.22	110.09

Analytical applications

The cited medication was successfully identified in commercial dosage forms (tablets and syrup). Four concentrations of the preparations' solutions were obtained, and the solutions underwent the same procedures as when a calibration curve was created. The recoverability and relative standard deviation were then computed, as shown in the table 3.

Table 3: Direct method to the pharmaceutical preparation

Preparative drug	Taken TRP µg/mL	Found TRP µg/mL	Recovery %
Actifeen ® syrup	6	5.937	98.96
	10	9.933	99.33
	16	16.057	100.35
	20	19.837	99.18
Mean±SD %	99.455± 0.611		
N	4		
Variance	0.373		
%SE	0.305		
%RSD	0.614		
Preparative drug	Taken TRP µg/mL	Found TRP µg/mL	Recovery %
Kindifed ® tablets	6	6.009	100.15
	10	9.885	98.85
	16	15.794	98.71
	20	19.645	98.22
Mean±SD %	98.982 ± 0.823		
n	4		
Variance	0.678		
%SE	0.411		
%RSD	0.831		

Tablet Content Uniformity Assay

The uniformity of the triprolidine hydrochloride concentration in its tablets has been examined using the solution's absorption. Ten individual tablets (Kindified 2.5 mg, AL-KINDI, for pharmaceutical Ind./Baghdad/Iraq) were put in 50 mL volumetric flasks and dissolved in 50 mL of purified water. Two millilitres were then extracted from the finished solution, and measurements were taken in accordance with the procedures used in the ideal working method. The findings are shown as a percentage of recoveries, with a 98.79 ± 0.9487 standard deviation, as shown in Figure 9.

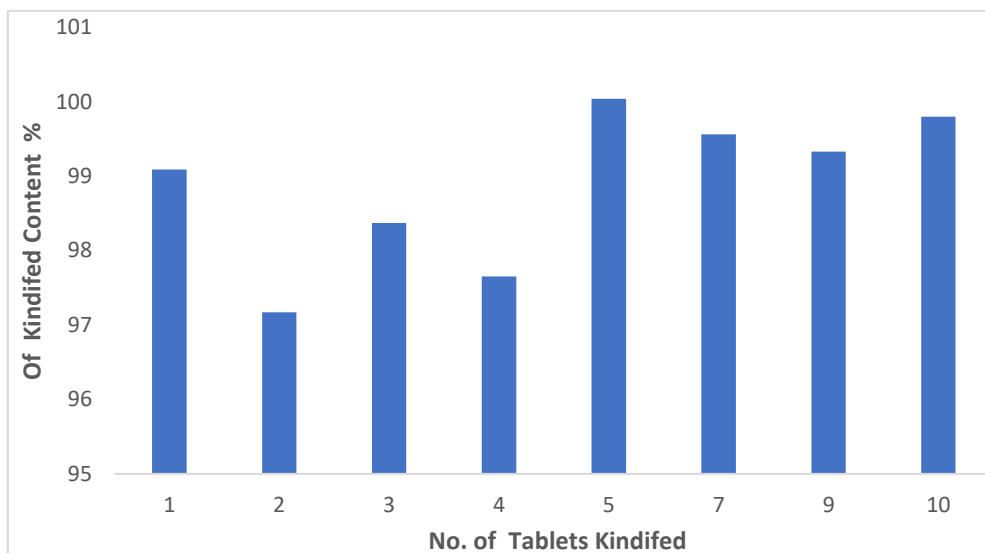


Figure 9: Content Uniformity Assay of Tablets (Kindified 2.5 mg)

Characterization techniques

Scanning electron microscopy SEM analysis

When evaluating the surface characteristics of nanoparticles, such as their size, shape, and distribution, scanning electron microscopy (SEM) and other electron microscopy techniques are crucial tools[10] Scanning electron microscope (SEM) imaging of silver particles shows clusters of irregularly shaped nanoparticles with dimensions ranging from 8 to 78 nm with a large gap, which indicates the high porosity of silver nanoparticles, which in turn increases the effectiveness of the particles for catalysis, adsorption, and other properties. As shown in Figure 10.

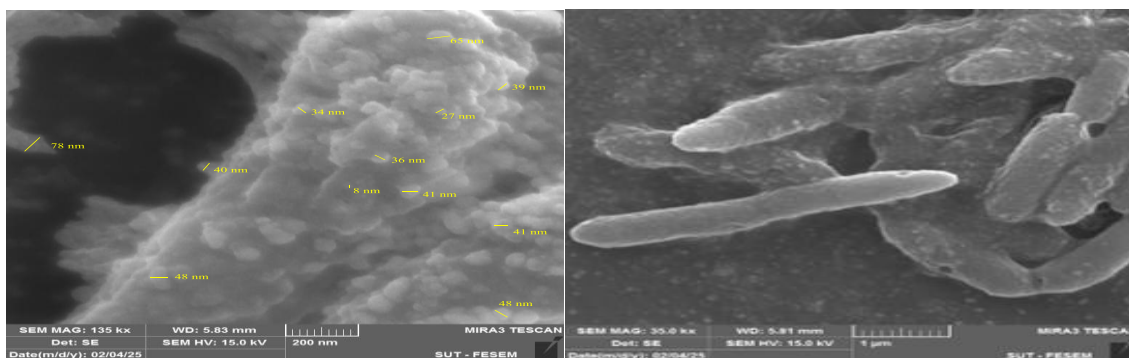


Figure 10: (SEM) of the silver nanoparticles

UV/VIS spectroscopy analysis

The generated silver nanoparticles may be successfully identified using UV-Vis spectroscopy. Previous research indicates that absorption spectra can confirm that the generated silver nanoparticles are present in solution [23]. A UV-Vis spectrometer (Shimadzu UV-1800) at a wavelength of 200–800 nm was used to detect the nanoparticles. [24] Silver nanoparticles (Ag^+) are reduced when sage leaf extract is added to the AgNO_3 solution, and the colour of the solution changes from light yellow to reddish brown, resulting in the formation of silver nanoparticles. Figure 11 shows the UV-Vis spectrum of the silver nanoparticles. It is well known that localized plasmon resonance gives noble metals unique optical characteristics. Silver nanoparticles' SPR absorption spectra were recorded at 445 nm, which is consistent with previous studies. [25, 26] After the surface of silver nanoparticles (AgNPs) was occupied with triprolidine hydrochloride (TRP), a wavelength shift occurred from 445 nm to 451 nm. This indicates a shift in the surface of silver nanoparticles as a result of their binding with triprolidine hydrochloride (TRP).

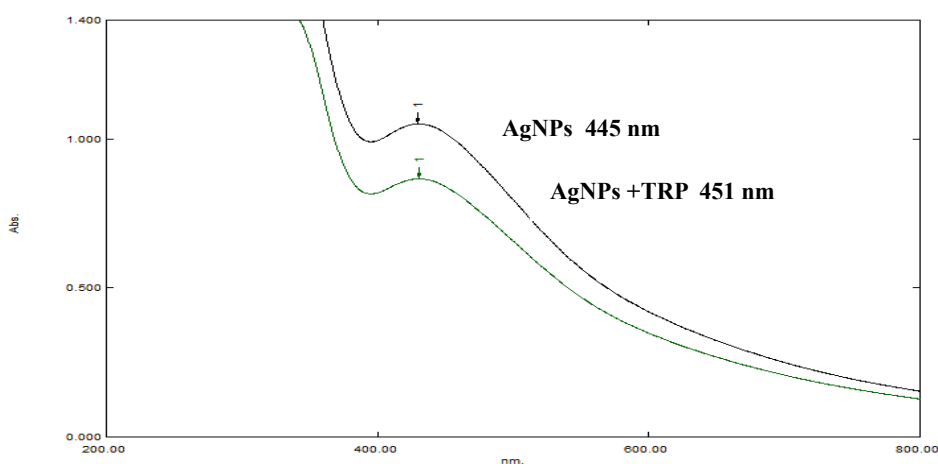


Figure 11: UV-VIS for AgNPs & AgNPs +TRP

(EDX) Spectrum analysis

X-ray diffraction analysis of silver nanoparticles prepared from sage extract showed the highest weight percentage of silver (56.56%), because the sample base is silver. Other peaks with lower weight percentages of carbon and oxygen were also revealed, attributed to organic compounds from the plant extracts. In addition, other minor percentages are attributed to the elements used in the measurement and sample preparation in the device. As shown in figure 12.

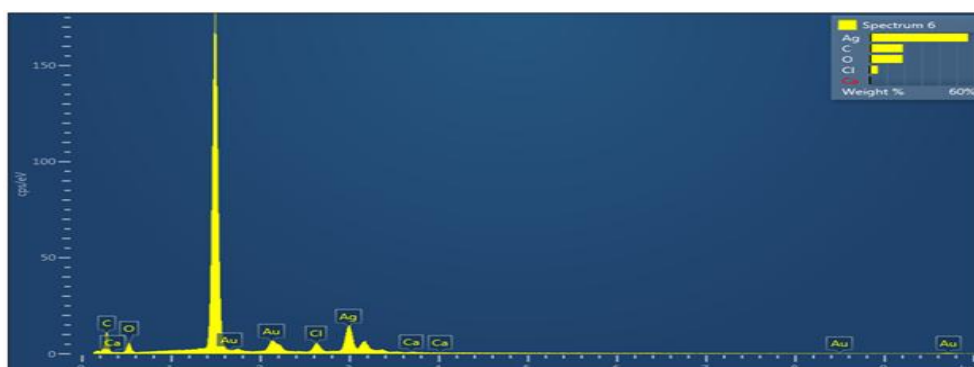


Figure 12: EDX spectrum of AgNPs.

FTIR spectroscopy analysis

FT-IR spectra of silver nanoparticles (AgNPs) produced from sage leaf extract were captured in order to identify the potential functional groups responsible for the biogenesis of the nanoparticles by FTIR spectroscopy in the wavelength range of 400-4000 cm^{-1} . The FTIR spectrum of the silver nanoparticles showed two strong bands ascribed to the water in the plant derivative, the first of which is a wide band in the range 3362-3539 cm^{-1} ascribed to the frequency of the O-H bond affected by hydrogen bonding (therefore a broad band appears) and the second at 1637 cm^{-1} ascribed to the bending frequency of the O-H bond. [27] It is also evident that there are two bands in the range (464-530 cm^{-1}) attributed to the silver nanoparticles and a weak band at 2893 cm^{-1} attributed to the frequency of the C-H bond resulting from the organic compounds present in plant extract. [28, 29] As shown in Figure 13.

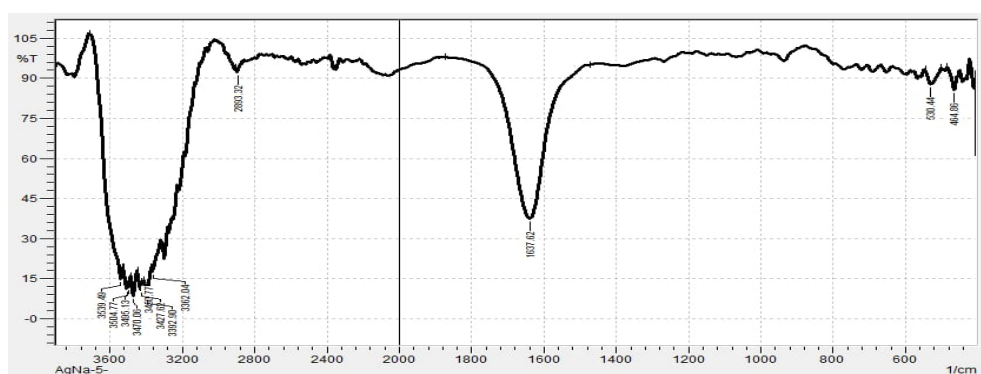


Figure 13: FTIR spectra of AgNPs

Conclusions

We successfully produced green nanomaterials in this study, and these methods have become more well-liked because they are inexpensive, simple to prepare, and devoid of potentially harmful substances. Furthermore, the results are improved when the medication is associated with silver nanoparticles. Additionally, a shift in wavelength from 445 nanometers (for AgNPs) to 451 nanometers (for the medicine) was observed when the drug triprolidine hydrochloride (TRP) was introduced to the AgNPs solution. This was an indication that the molecules were bonded to the medication solution. The suggested method is regarded as environmentally friendly since it uses inexpensive, environmentally friendly solvents to create Ag-NPs, which are used for the optical determination of the studied medications. Both pure and therapeutic dose versions of the medicines can be accurately identified using this procedure.

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طريقة مطيافية ضوئية تعتمد على التخليق الأخضر لتحديد هيدروكلوريد تريبروليدين في شكله النقي والمنتجات الصيدلانية باستخدام جسيمات نانوية فضية حيوية

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معلومات البحث:	الخلاصة:
تاريخ الاستلام:	تُعد الجسيمات النانوية المعدنية مثيرة للاهتمام بشكل خاص في مجال تكنولوجيا النانو نظرًا لخصائصها الكيميائية المميزة. كان الغرض من هذا العمل هو تطوير طريقة بسيطة ومنخفضة السمية وغير مكلفة لتحديد هيدروكلوريد التريبيروليدين (TRP) في الأشكال الصيدلانية والجرعات النقية. تستخدم الدراسة الحالية مستخلصًا مائيًا من أوراق المريمية الطبية (<i>Salvia officinalis</i>) لإنتاج جسيمات نانوية فضية (AgNPs) بطريقة خضراء. أجريت القياسات الطيفية بالأشعة فوق البنفسجية-المرئية (UV-Vis) والأشعة تحت الحمراء (IR) في قسم الكيمياء، كلية العلوم، جامعة تكريت، بينما تم إجراء الفحوصات الأخرى في مختبرات متخصصة في إيران، وذلك في الفترة من 28 أكتوبر 2024 إلى 5 مارس 2025. أظهرت النتائج الطيفية أن أقصى امتصاص لخليط الجسيمات النانوية مع الدواء كان عند 451 نانومتر، مع علاقة خطية قوية ضمن نطاق التركيز (2-28 ميكروغرام/مل) وبمعامل ارتباط $R^2 = 0.9985$ بلغت الامتصاصية المولية 1.3160×10^4 لتر/مول.سم، وكانت قيمة دلالة ساندل 0.0239 ميكروغرام/سم ² . بلغ حد الكشف 0.1427 ميكروغرام/مل، وحد التقدير 0.4324 ميكروغرام/مل. أظهرت النتائج معدل استرجاع 99.304%، بانحراف معياري نسبي 0.599% وخطأ نسبي 0.255%. أثبتت الطريقة دقتها وموثوقيتها عند تطبيقها على أشكال جرعات صيدلانية مختلفة تحتوي على دواء تريبروليدين هيدروكلوريد.
تاريخ التعديل:	
تاريخ القبول:	
تاريخ النشر:	
الكلمات المفتاحية:	
تريبيروليدين-HCl، التخليق الأخضر، جسيمات نانوية فضية، التحليل الطيفي، المريمية الطبية	
معلومات المؤلف	
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