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SPECTROPHOTOMETRIC METHOD USING THE DERIVATIVE FOR THE DETERMINATION OF THE DRUG LOSARTAN

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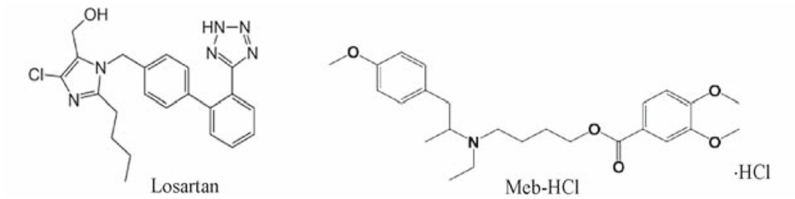
A sensitive, easy, and low-cost method used in the determination of pure forms of losartan and mebeverine hydrochloride, also in pharmaceutical preparations with derivative spectrometry using UV-Vis technology. This method depends on measuring the first derivative of the spectrum using zero cross, peak to base line, and peak area. The linear range of concentrations used was equal to 2–14 ppm for losartan, whereas for mebeverine hydrochloride it was equal to 2–16 ppm in a mixture. For losartan, in the presence of mebeverine hydrochloride, 12 ppm by utilizing peak to baseline correlation coefficients 0.9984, 0.9994, and peak area 0.9972, whereas for mebeverine hydrochloride in the presence of losartan, 12 ppm by utilizing peak to fundamental correlation coefficients 0.9952, 0.9966, 0.9957, and peak area 0.9970, 0.9971, 0.9968, 0.9971. The limit of detection for each drug, losartan and mebeverine hydrochloride, is equal to 0.0113 ppm. The accuracy and precision of the method were estimated by calculating relative standard deviation (%RSD) values less than 3% while maintaining a recovery percentage of acceptable value. The proposed method proved effective and efficient at estimating both losartan and mebeverine hydrochloride, in the presence of the other in a mixture of the two without interference, despite the closeness of their spectral absorption peaks. There are no other more accurate methods for estimating the two in a mixture than the proposed method. The proposed method is considered one of the most direct and economical methods that do not require reagents or additional materials for conducting reactions and studying the optimal conditions for those interactions. Thus, it is considered one of the green chemistry techniques that reduce the use of chemicals and reagents in the process of estimating these drugs in a mixture and in a shorter period of time. The proposed method can be used to estimate the different properties in a mixture of the two compounds whose absorption spectra are close.

Keywords: *losartan, method, determination, drug, spectrophotometric.*

Introduction. Losartan label ([2-Butyl-5-chloro-3-[[4-[2-(2H-tetrazol-5-yl)phenyl]phenyl]methyl]imidazol-4-yl] methanol), losartan is a non-peptide medicine that has a gradual and long-term antihypertensive effect by blocking angiotensin II receptors. Various commercial products contain losartan potassium such as Cozaar, Lortaan, Neo-Lotan (Merck & Co.), Losaprex (Sigma Tau), Oscaar (Riesel), Lavestra (Hungary), Lorista (Bulgaria and Romania), Losartan Kalium TAD (Germany), Losartan Krka (Denmark, Greece, Italy and France), Lozitar (Pinewood laboratories Ltd.). Losartan belongs to the group of antihypertensive therapeutic drugs. It blocks the angiotensin receptors; thus, it is also called an angiotensin II receptor blocker (ARB). Losartan is a selective type I angiotensin II receptor (AT1) antagonist and inhibits the binding of angiotensin II to its type I receptors in the tissue (adrenal glands and kidney). Losartan and its active metabolites E-3174 are very potent vasodilators and inhibitors of aldosterone (normally AT1 → vasoconstriction + aldosterone) leading to sodium and water retention of losartan [1–4].



Losartan Meb-HCl

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Many methods have been developed to determine the presence of losartan utilizing UV-Vis technology [1–3, 5–12], HPLC [4, 13–18], UPLC [19], UPLC–MS/MS [20, 21], MELC [22], and LC-MS/MS [23–25].

Mebeverine hydrochloride (Meb-HCl) is named 3,4-dimethoxy benzoic acid ethyl 2,4 methoxy 4-phenyl-1-methyl ethyl amino-butyl ester in the IUPAC. Meb-HCl is widely utilized as a relaxant and antispasmodic medication of the gastrointestinal tract, especially for colonic spasms and irritable bowel syndrome [26, 27]. It is a crystalline white powder that has a molecular weight equal to 466 g/mol, its formula is $C_{25}H_{35}NO_5 \cdot HCl$. Meb-HCl dissolves in water and ethanol, but does not dissolve in diethyl ether [28, 29].

Various methods have been used to estimate mebeverine hydrochloride (Meb-HCl), such as UV-Vis [29–33], HPLC [34–36], potentiometry [37–39], and CFIA [40–42]. The derivative spectrometry method has been used by several researchers as a sensitive and simple estimation method [43–50].

Owing to the different ways in which each of the two drugs losartan and Meb-HCl were estimated individually, in this work, it was necessary to estimate each drug by the presence of the other in a mixture of them using a simple and easy method because of their spectrum overlaps. No other method was found to be more accurate than the developed method for their estimation in a mixture of both in the presence of this spectrum overlap.

Experimental. All materials used are high-purity analytics dissolved in distilled water. Losartan and Meb-HCl, glucose, sucrose, and starch were obtained from SDI (Samara, Iraq). Losartan tablets (50 mg) were used from two companies, Pioneer (Iraq) and Micro Labs (India), whereas Meb-HCl tablets (135 mg) were used from two companies, Jeddah (Saudi Arabia) and Abbott (France).

The standard solution for each of the two drugs was prepared with 0.01 g of each drug dissolved in distilled water, then quantitatively transferred to a 100-mL volumetric vial and diluted to the mark with distilled water, and from here onward the rest of the concentrations used in the research were prepared by dilution using the same solvent.

Ten tablets of each drug were taken, weighed and ground, and then mixed with the other drug. The weight was equivalent to one tablet. Next, the mixture was dissolved in distilled water and heated slightly to ensure complete dissolution of the drugs, and then the volume was supplemented with distilled water to 100 mL and filtered to get rid of insoluble additives. The concentration of the filtrate was 100 ppm, and the concentrations used in the applications were prepared from this.

The device used for the measurement is a UV-Vis spectrophotometer double-beam model 1800 (Shimadzu, Japan). The utilized cell is made of quartz with a volume of 1 mL. The device measures a range of wavelengths ranging from 190 to 1100 nm.

A series of losartan 2–14 ppm and mebeverine hydrochloride 2–16 ppm solutions were prepared by utilizing the zero-order method scanning at 200–350 nm to take the absorption peaks for each drug (losartan and Meb-HCl).

The first step was to transfer different volumes of losartan (0.1–0.7 mL) into seven volumetric vials of 5 mL each containing a fixed volume of Meb-HCl (0.6 mL).

The second step was to transfer different volumes of Meb-HCl (0.1–0.8 mL) into eight volumetric vials of 5 mL each containing a fixed volume of losartan (0.6 mL). All concentrations used were prepared from a standard solution of 100 ppm and diluted with distilled water; we also measured the first derivative of the spectrum.

Results and Discussion. Figure 1a shows a spectrum of pure losartan at a wavelength of 205.8 nm, Meb-HCl at a wavelength of 221 nm, and a mixture of the two drugs at a wavelength of 257.6 nm. The first derivative of the spectrum results for both drugs are shown in Table 1.

The two drugs losartan and Meb-HCl cannot be estimated using zero-order absorption at the same time in a mixed solution; therefore, the first derivative of the spectrum method was successfully used to display idealized spectra for individual and combinations of drugs in Fig. 1b.

The calibration curve was plotted to find the values of the derived spectra, in particular, the sparse charts zero order, peak to base line, and peak area were used. Analysis of losartan and Meb-HCl in this set was carried out for each drug and also for the mixed solution of both drugs. Figure 2 and Tables 2 and 3 display the analytical factors for the determination of each drug by using the first derivative of the spectrum.

The results obtained from the analysis of losartan 2–14 ppm with Meb-HCl 12 ppm and Meb-HCl 2–16 ppm with losartan 12 ppm using derivative spectrometry (Fig. 3).

To verify the accuracy of the developed method, simple statistical calculations were used. It was measured five times for each of the two drugs, using different concentrations, using the first derivative of the spectrum method. The analytical method used shows that it was suitable for the simultaneous determination of losartan and Meb-HCl in different samples. The results are shown in Table 4.

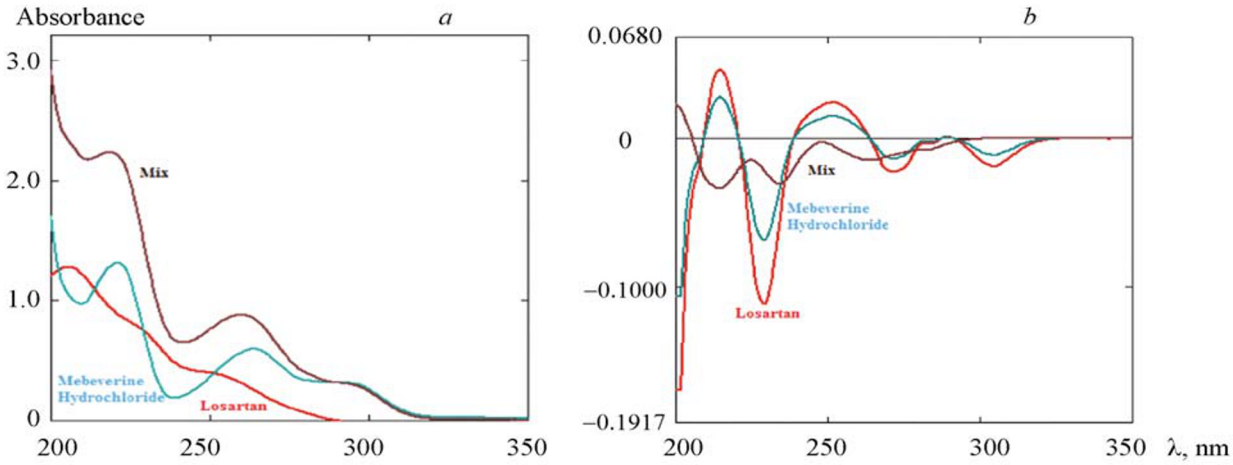

Fig. 1. Zero-order (a) and first-order derivative (b) pure losartan 8 ppm, pure mebeverine hydrochloride 20 ppm, and a mixture of losartan 8 ppm with mebeverine hydrochloride 20 ppm.

TABLE 1. Statistical Analysis of the Determination of Losartan and Mebeverine Hydrochloride

Drug	Calculation method	λ, nm	Regression equation	*r*	Slope
Losartan	Peak to base line	224.6	$y = -0.0012x+0.0051$	0.9983	−0.0012
	Peak to base line	247.8	$y = -0.0003x-0.0008$	0.9990	−0.9990
	Peak area	233.4–262.8	$y = 0.0253x+0.1098$	0.9981	0.0253
	Zero cross	205.4	–	–	–
Mebeverine hydrochloride	Peak to base line	214.6	$y = 0.0024x-0.0015$	0.9986	0.0024
	Peak to base line	252	$y = 0.0013x-0.0007$	0.9987	0.0007
	Peak to base line	272	$y = -0.0012x+0.0012$	0.9988	0.0012
	Peak to base line	304.8	$y = 0.0013x-0.0007$	0.9987	0.0013
	Peak area	209.2–220.6	$y = 0.0182x-0.0125$	0.9986	0.0182
	Peak area	220.6–238.4	$y = -0.0588x+0.0403$	0.9988	0.0067
	Peak area	238.4–265.4	$y = 0.0279x-0.0219$	0.9985	0.0279
	Peak area	296.2–318.8	$y = -0.0089x+0.0084$	0.9990	0.0089
	Zero cross	209.249	–	–	–
	Zero cross	220.668	–	–	–
	Zero cross	238.739	–	–	–
	Zero cross	263.352	–	–	–
	Zero cross	391.547	–	–	–

A stock solution (1000 ppm) of 1 mL of the interfering agent was transferred to a volumetric vial of 5 mL capacity to the 10-ppm solutions of losartan, a volume of 1 mL of all other interfering components added to the solution containing 10 ppm of losartan. The same interfering substances were added to 12 ppm of a Meb-HCl solution. The measured solutions showed that there was no significant effect of the interfering agent according to the proposed method. Table 5 shows the results obtained.

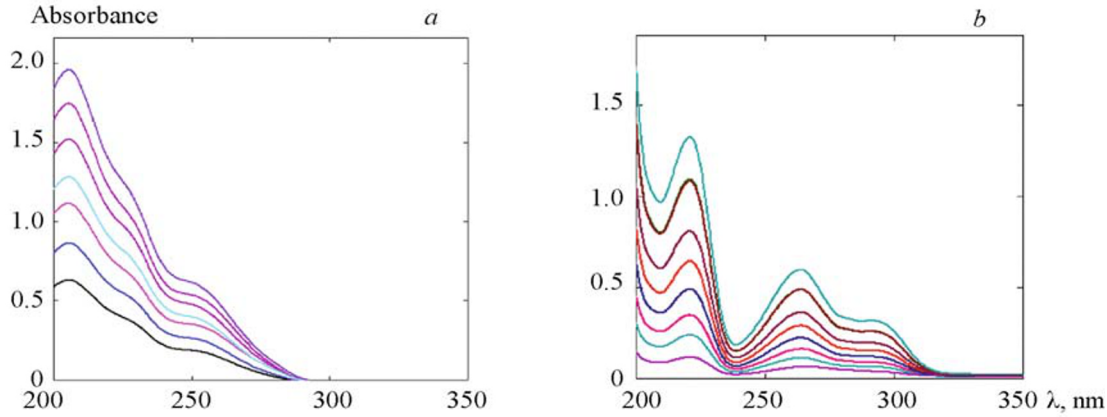

Fig. 2. Spectra of (a) losartan 2–14 ppm and (b) mebeverine hydrochloride 2–16 ppm utilizing the zero-order method.

TABLE 2. Estimation of Losartan 2–14 ppm in the Presence of 12 ppm Mebeverine Hydrochloride Utilizing the First Derivative of the Spectrum

Analysis method	λ, nm	Regression equation	*R*
Zero cross	205.4	–	–
Peak to base line	224.6	$y = -0.0028x - 0.012$	0.9984
Peak to base line	247.8	$y = -0.0003x - 9 \times 10^{-5}$	0.9994
Peak area	233.4–262.8	$y = 0.0096x + 0.0481$	0.9972

TABLE 3. Determination of Mebeverine Hydrochloride 2–16 ppm in the Presence of 12 ppm Losartan Utilizing the First Derivative of the Spectrum

Analysis method	λ, nm	Regression equation	*R*
Zero cross	214.6	$y = 18.617x - 0.6882$	0.9964
Peak to baseline	252	$y = 36.688x + 0.2513$	0.9952
Peak to baseline	272	$y = -37.021x - 0.3474$	0.9966
Peak to baseline	304.8	$y = -45.068x + 0.0443$	0.9957
Peak area	209.2–220.6	$y = 0.0202x - 0.1031$	0.9970
Peak area	220.6–238.4	$y = 0.0653x + 0.05$	0.9971
Peak area	238.4–265.4	$y = 0.0309x + 0.1836$	0.9968
Peak area	296.2–318.8	$y = -0.0096x + 0.0196$	0.9971
Zero cross	209.249	–	–
Zero cross	220.668	–	–
Zero cross	238.739	–	–
Zero cross	263.352	–	–

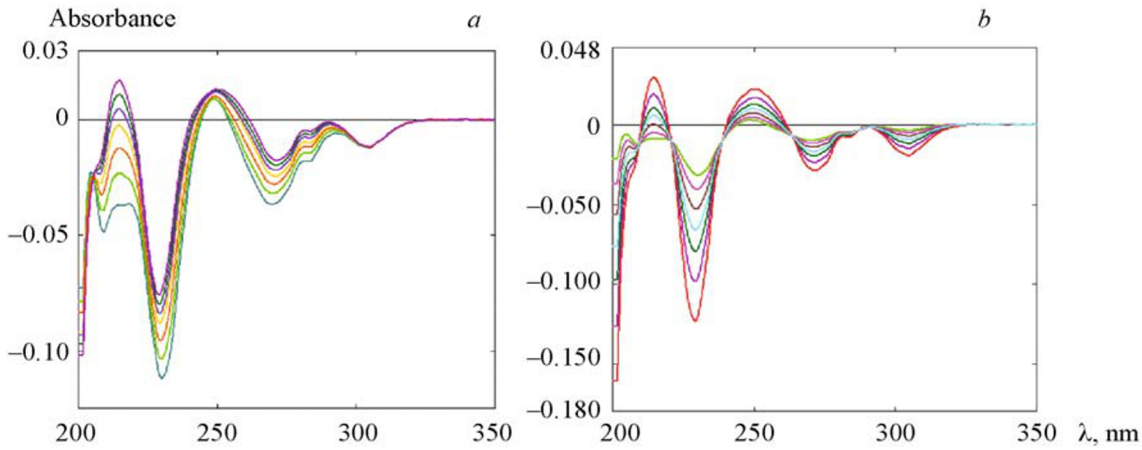

Fig. 3. The first derivative of the spectrum for (a) losartan 2–14 ppm in the presence of mebeverine hydrochloride 12 ppm and (b) mebeverine hydrochloride 2–16 ppm in the presence of losartan 12 ppm.

TABLE 4. Precision and Accuracy in the Method Used for the Determination of Losartan and Mebeverine Hydrochloride in a Mixture of Using the First Derivative of the Spectrum for $n = 5$

Drug	Analysis method	λ, nm	Concentration, ppm		RSD%	Rec.%
			taken	found		
Mebeverine hydrochloride	Peak to baseline	214.6	4	3.947	1.544	98.675
			8	8.077	0.980	100.962
	Peak area	220.6–238.4	4	4.061	1.390	101.525
			8	8.168	2.085	102.100
Losartan	Peak to baseline	224.6	2	1.957	2.813	97.650
			10	9.957	0.582	99.570
	Peak area	240.4–259	2	2.087	1.957	104.350
			10	10.060	0.551	100.600

TABLE 5. Effect of Interferences on the Estimation of Losartan and Mebeverine Hydrochloride

Drug	Interferences	Concentration, ppm		Rec.%
		taken	found	
Mebeverine hydrochloride	Glucose	12	11.998	99.983
	Sucrose		12.090	100.75
	Starch		11.992	99.933
Losartan	Glucose	10	10.010	100.10
	Sucrose		10.002	100.02
	Starch		9.999	99.990

Note. Detection limit (DL) was calculated using the slope method. DL = $3S_B$/slope. S_B = standard deviation of distilled water for $n = 13$. Limit of detection for every drug equal to 0.0113 ppm.

TABLE 6. The First Derivative of the Spectrum Estimation of Losartan and Mebeverine Hydrochloride

Compound	Calculation method	λ, nm	Taken, ppm	Found, ppm	Rec.%	%RSD
Mebeverine hydrochloride, Jeddah, Saudi 135 mg	Peak area	220.6–238.4	4	4.06	101.50	0.651
Duspatalin, Abbott, France 135 mg	Peak area	220.6–238.4	4	3.99	99.75	0.264
Losartan, Pioneer, Iraq 50 mg	Peak area	240.4–259	10	9.98	99.89	1.101
Losartan, Micro, India 50 mg	Peak area	240.4–259	10	10.01	100.10	0.176

Applications. Analytical applications of the derivative spectrometry method utilized in this research to estimate losartan and Meb-HCl in tablet form succeeded in analyzing the content of these compounds in tablets. Each taken from sample concentration, the comparison was made to show whether there was any effect on the origin of the sample. Table 6 displays the results. The suggested method can also be used to estimate any two drugs in pharmaceutical preparations in the form of tablets manufactured by other companies. The practical part of the research, including applications, was conducted within the college laboratories to which we are affiliated, not in the laboratories or companies that manufacture these medicines. Samples of the medications on which the applications were performed were manufactured by several companies and were obtained from local Iraqi pharmacies.

Conclusions. The method is derived from simple and low-cost procedures, in addition to its high sensitivity in the determination of losartan and Meb-HCl directly in a mixture without interference, despite the closeness of their absorption peaks. Through the results obtained, the method proved its efficiency in the evaluation of both drugs, one in the presence of the other in a mixture of both, and it is the only method that can be used in estimating them in a mixture without overlapping. This is an advantage not found in other methods.

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