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UV SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF FEXOFENADINE IN BULK AND TABLET DOSAGE FORM

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ABSTRACT
A simple and economical Spectrophotometric method has been developed for the estimation of Fexofinadine in bulk form as well as marketed formulations. The present UV method is based on the measurement of absorption at a maximum of 259 nm using 2-propanol as a solvent. The stock solution of Fexofinadine was prepared and subsequent suitable dilution was prepared in 2-propanol to obtain a standard curve. The standard solution of Fexofinadine shows absorption maxima at 259 nm. The estimation of Fexofinadine was done at 259 nm in 2-propanol using a UV-visible double-beam spectrophotometer. In the developed method, linearity over the concentration range of 0.1-1.5 µg/ml of Fexofinadine was observed and was found in agreement with Beer's law. The linear regression was found to be 0.998 and the percentage purity was also determined at 101%, which was within the limit as per the IP. It could be concluded from the results obtained in the present investigation that the method for estimation of Fexofenadine in pure form and in pharmaceutical dosage form is simple, rapid, and economical and can be used, successfully, in the quality control of pharmaceutical formulations and other routine laboratory analysis.

KEYWORDS: UV spectrophotometric, Linear regression, Pharmaceutical dosage, Fexofenadine and Quality control.

1. INTRODUTION

Spectroscopy is the field of study that measures and interprets the electromagnetic spectra that result from the interaction between electromagnetic radiation and matter as a function of the wavelength or frequency of the radiation.[Kroto,1975; Bunker and Jensenet, 2006; Bunker and Jensenet, 2006; Wilson et al., 1980; Skoog et al., 2007; Herrmann and Onkelinx, 1986], Matter waves and acoustic waves can also be considered forms of radiative energy, and recently gravitational waves have been associated with a spectral signature in the context of the Laser Interferometer Gravitational-Wave Observatory (LIGO).[Bartusiak, 2017].

In simpler terms, spectroscopy is the precise study of color as generalized from visible light to all bands of the electromagnetic spectrum. Historically, spectroscopy originated as the study of the wavelength dependence of the absorption by gas phase matter of visible light dispersed by a prism. Spectroscopy, primarily in the electromagnetic spectrum, is a fundamental exploratory tool in the fields of astronomy, chemistry, materials science, and physics, allowing the composition, physical structure, and electronic structure of matter to be investigated at the atomic, molecular and macro scale, and over astronomical distances. Important applications include biomedical spectroscopy in the areas of tissue analysis and medical imaging. Spectroscopy is a branch of science concerned with the spectra of electromagnetic radiation as a function of its wavelength or frequency measured by spectrographic equipment, and other techniques, to obtain information concerning the structure and properties of matter[Lindberg and Grace, 2002].

Although color is involved in spectroscopy, it is not equated with the color of elements or objects which involve the absorption and reflection of certain electromagnetic waves to give objects a sense of color to our eyes. Rather spectroscopy involves the splitting of light by a prism, diffraction grating, or similar instrument, to give off a particular discrete line pattern called a "spectrum" unique to each different type of element. Most elements are first put into a gaseous phase to allow the spectra to be examined although today other methods can be used on different phases. Each element that is diffracted by a prism-like instrument displays either an absorption spectrum or an emission spectrum depending upon whether the element is being cooled or heated. [Obrien, 2022].

Until recently all spectroscopy involved the study of line spectra and most spectroscopy still does [Sutton, 1974]. Vibrational spectroscopy is the branch of spectroscopy that studies the spectra [Vucelic radovic et al., 2019]. However, the latest developments in spectroscopy can sometimes dispense with the dispersion technique. In biochemical spectroscopy, information can be gathered about biological tissue by absorption and light scattering techniques. Light scattering spectroscopy is a type of reflectance spectroscopy that determines tissue structures by examining elastic scattering [Perelman et al., 1998].

In such a case, it is the tissue that acts as a diffraction or dispersion mechanism. Spectroscopic studies were central to the development of quantum mechanics, because the first useful atomic models described the spectra of Hydrogen which models include the Bohr model, the Schrödinger equation, and Matrix mechanics which all can produce the spectral lines of Hydrogen, therefore, providing the basis for discrete quantum jumps to match the discrete hydrogen spectrum. Also, Max Planck's explanation of blackbody radiation involved spectroscopy because he was comparing the wavelength of light using a photometer to the temperature of a Black Body [Kumar, 2008]. Spectroscopy is used in physical and analytical chemistry because atoms and molecules have unique spectra. As a result, these spectra can be used to detect, identify and quantify information about the atoms and molecules. Spectroscopy is also used in astronomy and remote sensing on Earth. Most research telescopes have spectrographs. The measured spectra are used to determine the chemical composition and physical properties of astronomical objects (such as their temperature, density of elements in a star, *velocity*, black holes and more), [Hungund, 2020] An important use for spectroscopy is in biochemistry. Molecular samples may be analyzed for species identification and energy content. [Nonell and viappiani, 2008].

The ultraviolet spectroscopy is a robust, workhorse method for the quantification of drugs in formulations where there is no interference from excipients. Fexofenadine, a,a-Dimethyl-4-[1-hydroxy-4-[4-(hydroxydiphenyl-methyl) -1-piperidinyl] butyl]-benzene acetic acid (The Merck 2001; Fig. 1) is the active carboxiylic acid analog of the antihistamine terfenadine.

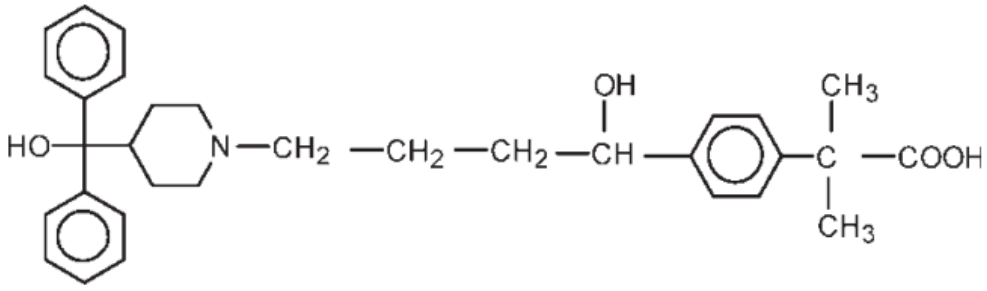

Fig. 1: Chemical structure of Fexofenadine.

It shares the histamine H1 receptor antagonist and nonsedative properties of the parent compound, but does not affect the cardiovascular events. Fexofenadine is a useful addition to available treatments of allergic diseases as allergic rhinitis and chronic urticaria, with a wider margin of safety (Markham and Wag staff, 1998; Amichai et al., 2001; Estelle and Simons 2002; Simpson and Jarvis 2000). Besides, recently studies have shown that fexofenadine is also useful for treatment of asthma (Borade et al., 2006) and atopic dermatitis (Kawashima and Harada, 2007). There are some HPLC methods reported in the literature for the determination of fexofenadine in biological fluids with mass spectrometry detection (Hofmann et al., 2002), ionspray tandem mass spectrometry detection (Gergov et al., 2001; Fu and Woolf, 2004), and fluorescence detection (Uno et al., 2004). Few methods reported the measurement in pharmaceutical dosage forms. Some HPLC methods, using ultraviolet detection, were described (Radhakrishna and Reddy, 2002; Breier et al., 2004). Two capillary electrophoresis methods were also reported (Breier et al., 2005; Mikus et al., 2005). The quantitation of fexofenadine using spectrophotometric methods with detection in the visible region, based on the formation of complex reactions of fexofenadine with different compounds was published (Gazy et al., 2002). However, there is no work concerning the UV spectrophotometric determination of fexofenadine.

The purpose of this work is to present the development of a simple and fast Spectrophotometric method to quantify fexofenadine in coated tablets. The UV spectrums obtained through the analysis of the Fexofenadine solutions in the maximum of 259 nm (Fig.2).

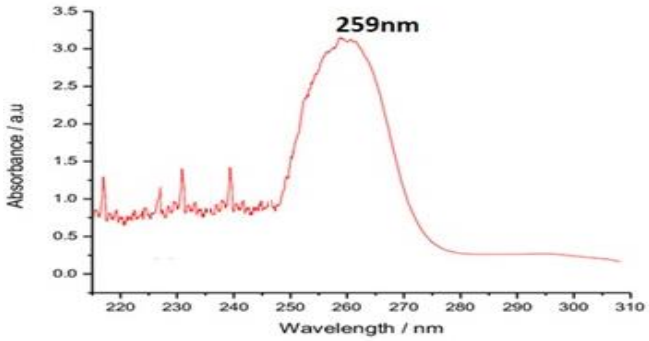

Figure 2: UV spectrums of fexofenadine hydrochloride standard solution.

2. MATERIAL METHODS

2.1. Experimental section

2.1.1. Samples

Fexofenadine hydrochloride substance reference (99.60%) was obtained from Hetero pharma Pvt.Limited (Hyderabad, Telanagana).

2.1.2. Spectrophotometric method or fexofenadine hydrochloride

Allegra® coated tablets for oral administration, containing fexofenadine hydrochloride (120 mg/tablet), and pregelatinized starch, croscarmellose sodium, and microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, hydroxypropyl methylcellulose, povidone, titanium dioxide, polyethylene glycol, pink iron oxide blend, yellow iron oxide blend as excipients, were commercially available. Analytical reagent grade chemicals were used.

2.1.3. Instrumentation and Conditions

Spectral and absorbance measurements were made with a UV-VIS Biochrome model UV S70, with 10 mm quartz cells and detection at 259 nm.

2.1.4. Standard solutions preparation

The standard solutions were prepared using an amount of powder equivalent to 10 mg of fexofenadine hydrochloride reference standard that was transferred to a 10 ml volumetric flask, marking up to volume with 2-propanol (1 mg/ml,1000µg/mL). Aliquots of this standard solution (0.1; 0.4; 0.6; 0.8; 1, and 1.5 ml) were transferred volumetrically into 10 ml flasks, marking up to volume with 2-propanol, obtaining final concentrations of 10.0; 40.0; 60; 80.0; 100.0 and 150.0 µg/mL, respectively. The determinations were conducted in triplicate.

2.1.5. Sample solutions preparation

To the sample solutions preparation, 20 tablets were weighted. An amount of powder equivalent to 10 mg of fexofenadine hydrochloride, for each pharmaceutical formulation, was transferred to 10 ml volumetric flask with 2-propanol (1 mg/ ml). Aliquots of 2.8 ml were transferred to 10 ml volumetric flasks and diluted with 2-propanol to give final concentration of 280.0 µg/mL. All determinations were conducted in triplicate.

3. RESULTS AND DISCUSSION

In this work, a method based on ultraviolet spectroscopy was developed for fexofenadine hydrochloride in coated tablets. In recent years, the development of spectrophotometry methods for determinations of drugs has increased considerable, due to their importance, low cost, and simplicity.

The experimental conditions were chosen after testing the different parameters that influence the analysis. The choice of the best solvent for samples was accomplished prime. Considering the solubility of fexofenadine in 2-propanol was tested as diluents, was used, since provides high absorbance values, and is less toxic. To assess the linearity, a standard curve for fexofenadine hydrochloride was constructed by plotting concentrations (µg/mL) versus absorbance and showed good linearity on the 0.10-1.5.0 µg/mL. The representative linear equation for this drug was y=0.313x þ 0.003, where x is concentration and y is the absorbance. The correlation coefficient was r = 0.998, indicating good linearity and they were depicted in Table 1 and Figure3.

Table 1: Absorbance of standard dilutions of fexofenadine.

S. No	Concentration Fexofenadine (µg/ml)	Absorbance
1	0	0.0
2	0.1	0.024
3	0.4	0.118
4	0.6	0.199
5	0.8	0.248
6	1	0.304
7	1.5	0.470

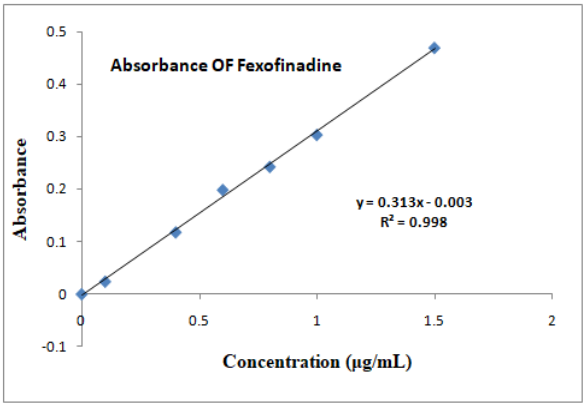

Fig. 3: Calibration curve for Fexofinadine.

Table 2: Experimental values obtained in quantitation of fexofenadine hydrochloride in capsules and coated tablets by UV Spectrophotometry at 259 nm.

Experimental amount			
mg/tablet)	**(%)**	**Mean**	**%RSD**
119.5	99.583	99.568	0.319
119.25	99.375		
120	100		
119.1	99.25		
119.88	99.9		
119.16	99.3		

The UV method was performed through the statistical t-student test at 0.05 significance level of the mean experimental values obtained in the quantification of fexofenadine hydrochloride in tablets by each method. The obtained results are given in Table 2. The UV method can be employed to the routine quality control of this drug in pharmaceutical dosage forms.

4. CONCLUSION

The results indicated that the UV spectrophotometric assay hold linearity at concentration ranging from 0.1 to 1.5, 1000 µg/ml. The UV method, which confirm the valid and useful to the routine quality control of fexofenadine hydrochloride in the formulations studied.

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