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Research Article

Novel Eco-Friendly Spectrophotometric Determination of Guaifenesin in Pharmaceutical preparations and Environmental Wastewater Samples: Application to content uniformity testing

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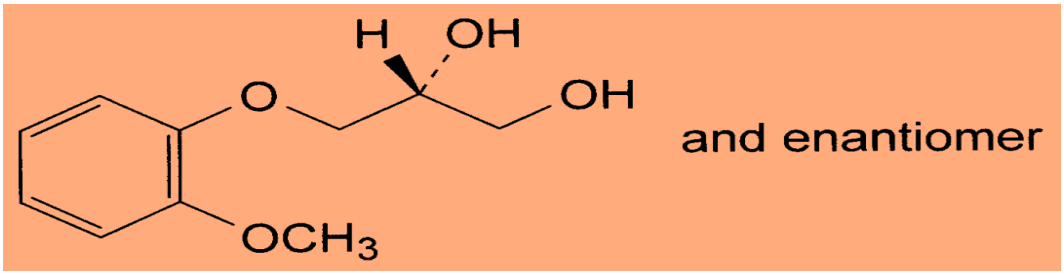
Abstract

A simple, precise, accurate, rapid, economical and sensitive ultraviolet spectrophotometric method has been developed for the determination of guaifenesin in pharmaceutical preparations and environmental wastewater samples, which shows maximum absorbance at 222 nm in water. Beer's law was obeyed in the range of 2-40µg/ ml, with molar absorptivity of 0.75 $\times 10^4$ L.mol^{-1}.cm^{-1}, relative standard deviation of the method was less than 1.4%, and accuracy (average recovery %) was 100 ± 1.0. No interference was observed from common excipients and additives often accompany with guaifenesin in pharmaceutical preparations. The method was successfully applied to the determination of guaifenesin in some pharmaceutical formulations (Syrups and Tablets) and industrial wastewater samples. The proposed method was validated by sensitivity and precision which proves suitability for the routine analysis of guaifenesin in true samples. Application to content uniformity testing

Key words: body reactivity; early postnatally

Introduction

Guaifenesin is chemically known as 1,2- propanediol3-(2-methoxyphenoxy) (Scheme 1) Guaifenesin occurs as a white crystals or crystalline powder. [1], is an expectorant and widely used in the treatment of coughing and congestion caused by the common cold, bronchitis, and breathing illness.[2], Guaifenesin may help control symptoms but does not treat the cause of symptoms or speed recovery. Guaifenesin is in a class of medications called expectorants. It works by thinning the mucus and clear the airways. The usual does is 100 to 200 mg every 2 to 4 hours [3-5].



Molecular formula: $C_{10}H_{14}O_4$ =198.2

Scheme 1. Chemical structure of guaifenesin.

Analytical procedures for the determination of guaifenesin include titrimetric method[1], various spectrophotometric [6-13], HPLC[14-20], electro kinetic chromatography[21], Volta metric assay[22], Capillary gas chromatography[23,24] and ion pair high performance liquid chromatography methods are also reported in the literature for the estimation of guaifenesin[25].The present paper reports the development of a new UV method for determination of guaifenesin in different type of syrups, tablets and environmental water samples. Application to content uniformity testing.

Experimental

Apparatus

Shimadzu UV- 1700 pharmaspec (double beam) spectrophotometer with 1.0 cm quartz cells was used for absorption measurement.

Reagents

All chemical used were of analytical or pharmaceutical grade and guaifenesin standard material was provided from AL-hokamaa company for pharmaceutical industries (HPI) Mosul-Iraq.

guaifenesin standard solution 10ppm

This solution was prepared by dissolving 10 mg of guaifenesin in 1000 ml of distilled water in calibrated flask.

Determination of absorption maxima

The standard solution of guaifenesin (20µg/ml) was scanned in the range of 220-300 nm which shows maxima located at 222 nm (Figure.1). Therefore 222 nm wavelength was selected for the construction of calibration curve.

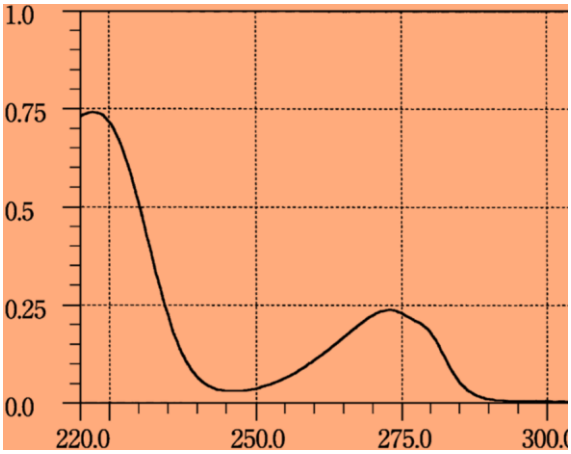


Figure 1: Absorption spectra of 20µg/ml guaifenesin against distilled water.

Recommended procedure

From the absorption maxima, calibration curve was prepared in the concentration range of 2-40 µg/ml. The absorbance was measured at 222 nm against distilled-water as a blank. The concentration of the sample solution can be determined by using the calibration curve

Procedures for pharmaceutical preparations (syrups):

Four different marketed guaifenesin syrup formulations (Exidil 30mg/5ml, Pulmocodain 100mg/5ml, Tussilet 50mg/5ml and Bronquium 30mg/5ml) were selected for analysis. The content of 5 bottles of each type were mixed well in 1L dried beaker. Aliquots equivalent to 5 mg of guaifenesin were transferred into 1L volumetric flasks and diluted with distilled water to the volume to get 5µg/ml solution and aliquot of this solution was treated as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

Procedure for pharmaceutical preparations (Tablets)

Weight and powder 10 tablets [Brawn tablet of Guaifenesin (100 mg)] Tablets-India]. Dissolve a quantity of the powdered tablets containing 0.01 gm. of guaifenesin in about 100 ml methanol and mixed for 20 mint and then filtered. The filtrate was mad up to 1000 ml with distilled water and aliquot of this solution was treated as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

Procedure for real water samples

To demonstrate the practical applicability of the proposed method, real water samples were analyzed by this method. Industrial waste water from AL-hokamaa company for pharmaceutical industries (HPI) Mosul-Iraq, were fortified with the concentrations in the range of 2,4,6 µg/ml of guaifenesin. The fortified water samples were analyzed as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

Result and Discussion

UV visible spectrophotometry is still considered to be a convenient and low-cost method for the determination of pharmaceuticals [26-32]. The method used for the determination of guaifenesin in pharmaceutical preparations and environmental wastewater samples was found to be sensitive, simple, accurate, and reproducible. Beer s law was obeyed in the concentration range of 2-40 µg/ml (Figure.2) with correlation coefficient of 0.997, intercept of 0.002 and slope of 0.0375. The conditional molar absorptivity was found to be $0.75x10^4$ l/mol.cm.

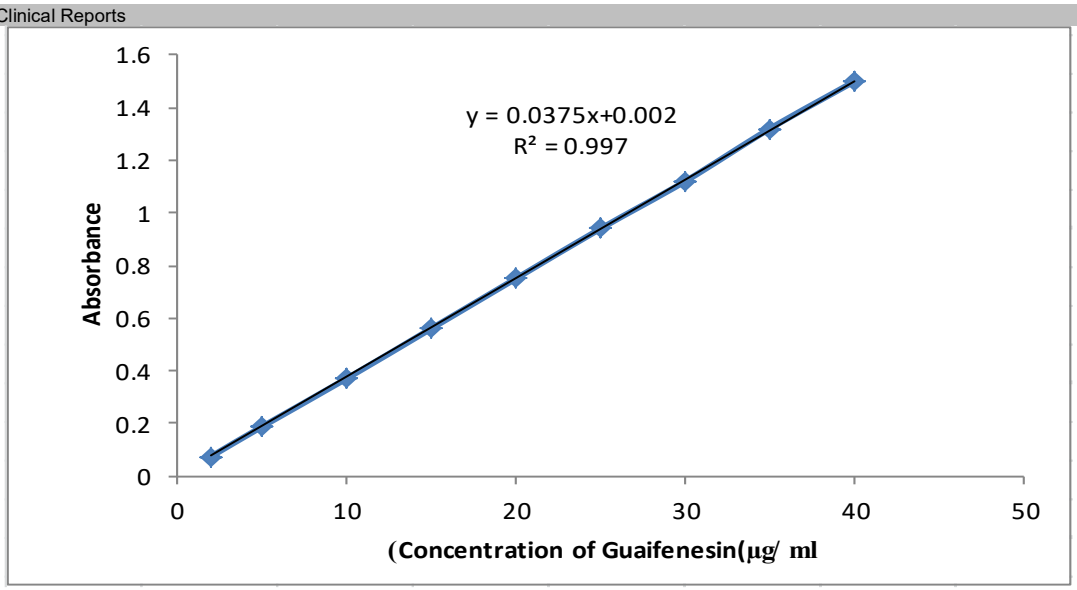


Figure 2: Calibration curve for Guaifenesin

Accuracy and precision of the method.

A pure drug solution was analyzed at three different concentrations; each determination being repeated six times. The relative error (%) and relative standard deviation values are summarized in (Table 1). From (table 1) the values of standard deviation were satisfactory and the recovery studies were close to 100%. The RSD% value is less than1.4 indicative of accuracy of the method.

Guaifenesin taken(µg/ml)(	Er (%) [a]	RSD (%)
2	1.1	1.3
3	1.2	41.
6	1.12	1.25

Table I: Accuracy and precision of the proposed method.

The proposed method was compared with other reported UV spectrophotometric methods and found to be superior and more sensitive than other methods (Table 2).

Parameters	Method 1	Method 2	Method 3	Method 4
Ref	7	8	11	Proposed
Max(nm)λ	272	274	273	222
Solvents	Methanol	H_2O	Methanol	H_2O
Linear range µg/ml	30-150	10 -50	5-40	2-40
(l/mol.cm)ε	$8.72x10^3$	$2.378x10^3$	$2.973x10^3$	$0.75 x10^4$
RSD%	Less than 2	----	0.74	Less than 1.4
Application	Tablets	Tablets	Tablets	Syrups, Tablets and industrial wastewater

Table 2: Comparison of the existing UV spectrophotometric methods with the proposed method for guaifenesin.

Analytical application

The proposed method was satisfactorily applied to the determination of guaifesein in its pharmaceutical preparations syrups, Tablets and wastewater samples, the results of the assay of the pharmaceutical preparations revels that there is close agreement between the results obtained by the proposed method and the label claim (Table3), and the results of water samples (Table 4) show that the recovery values obtained were closed to 100%.

Pharmaceutical formulations	Proposed method found*	Label amount
Exidil syrup (HPI)	6.03mg/ml	6 mg/ml
Pulmocodin syrup (NDI)	19.97 mg/ml	20 mg/ml
Tussilet syrup (HPI)	10.05 mg/ml	10 mg/ml
Bronquium(Ferrer)	6.0 mg/ml	6.0mg/ml
Tablets(100mg) (Brawn-India)	9.99	100mg/Tablet

***Mean of five determinations**

Table 3: Determination of guaifenesin formulations

Wastewater samples	Added µg/ml	Found* µg/ml	Recovery %(n=10)
Industrial wastewater	2	2.02	101
	4	3.97	99.25
	6	6.05	100.833

*** Mean value of ten determinations.**

Table 4: Determination of guaifenesin in industrial wastewater samples

Application of the method to content uniformity [33-37]

The proposed method proved to be suitable for the content uniformity test, where a great number of assays on individual tablets are required. Data presented in Table [5] indicate that the proposed method can accurately and precisely quantitate guifenesin in its commercially available tablets. The mean percentage (with RSD) of the labeled claim found in ten tablets was (0.14%) which fall within the content uniformity limits specified by the USP 33 [33].

Table [4]: Content uniformity testing of guifenesin tablets using the proposed method	% of the label claim
Tablet NO. 1	100. 16
Tablet NO. 2	100. 23
Tablet NO. 3	99. 88
Tablet NO. 4	100.41
Tablet NO. 5	99.38
Tablet NO. 6	99. 53
Tablet NO. 7	99.82
Tablet NO. 8	100. 15
Tablet NO. 9	100.26
Tablet NO. 10	100.16
Mean ($\bar{x}$)	99.998
% RSD	0.41
Max. allowed unit [33]	±1.4%

Conclusion

The developed method is found to be highly sensitive, accurate, simple, precise and economical, and can be used for routine quality control analysis of guifenesin in pure form, bulk, pharmaceutical formulations and environmental wastewater samples

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