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# A New and Sensitive UV Spectrophotometric Method for the Determination of Guaifenesin in Dosage Forms

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**Keywords:** U. V. Spectrophotometry, Validation, Guaifenesin, Dosage form

**ABSTRACT**

In the present study, a new and sensitive UV-spectrophotometric method is developed for an accurate, precise, economic and sensitive determination of Guaifenesin in dosage forms. Guaifenesin solutions are prepared in methanol solvent and absorbances are measured at 224.6 nm wavelength where Guaifenesin has maximum absorbance. In the concentration range of 2.5-15 µg/mL, it obeys Beer`s Law. From the linearity studies, the correlation coefficient, slope and standard deviation are calculated as 0.9999, 0.035, and 0.1933 respectively. The LOD and LOQ are evaluated and they are found to be within the limits. The present method is validated as per ICH guidelines.

## INTRODUCTION

Guaifenesin is (+)-3-(2-methoxy Phenoxy) - propane -1,2-diol. Its empirical formula is $C_{10}H_{14}O_4$ which corresponds to molecular weight of 198.21. It has slight bitter aromatic taste. The structure of Guaifenesin is represented as in Figure 1.

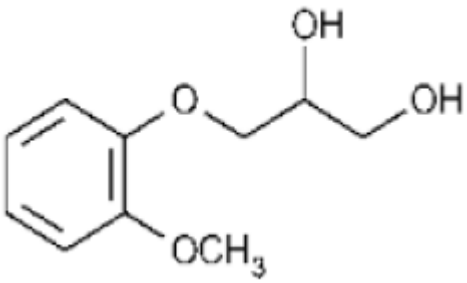


**Figure 1. Chemical structure of Guaifenesin**

It is used to relieve the chest congestion. It controls the symptom but does not treat the cause of the symptom. It is an expectorant and thinning the mucus and clear the air ways. The U.V. Spectra of Guaifenesin is represented in Figure 2.

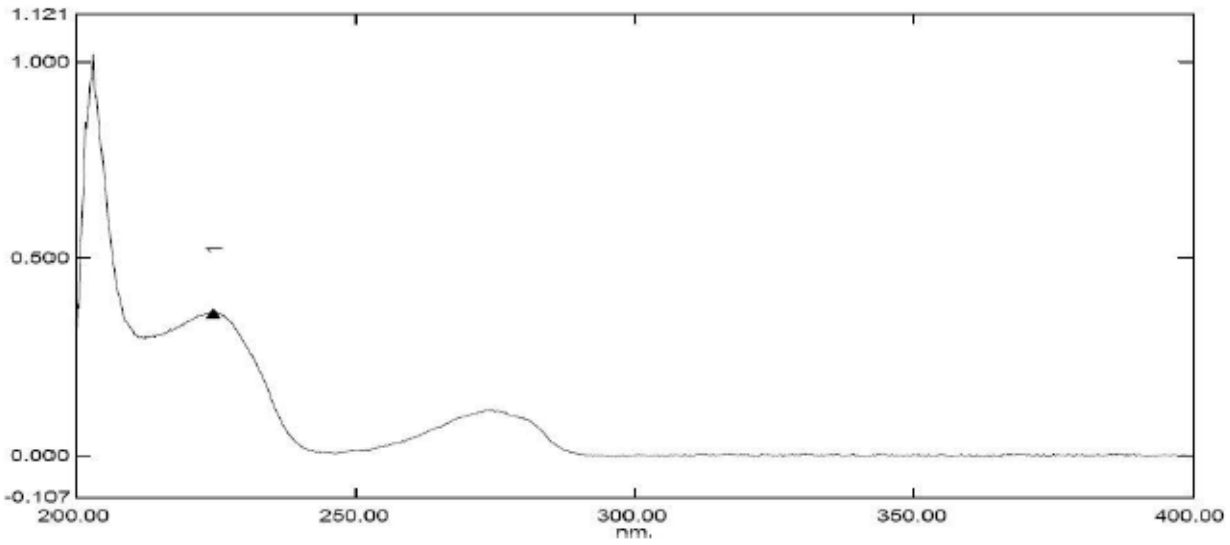


**Figure 2. U.V. Spectra of Guaifenesin**

As per literature survey, Guaifenesin was determined individually and with other compounds by RP-HPLC and LC-MS methods[1-8]. It was also determined simultaneously with other compounds by visible spectrophotometric method[9]. Visible spectrophotometric methods for simultaneous determination with other drugs[10-14] have also been developed. Guaifenesin exhibits absorption maxima at two wavelengths namely at 224.6 and 273 nm in UV region. Bhattacharya et al[15] determined Guaifenesin by stability indicating U.V. Spectrophotometric method along with its degradation products at a wavelength of 273 nm. In order to improve the sensitivity of the method, the authors have attempted to determine Guaifenesin at the wavelength of 224.6 nm where the absorbance of Guaifenesin is very high. The method was found to be simple and sensitive. The method has been successfully applied for the determination of the formulations of the drug.

## MATERIALS

Guaifenesin is a gift sample obtained from M/S Serin formulations, Hyderabad. Chemicals used in the method are of analytical grade and supplied by Bharath Scientific Company, Hyderabad.

### Preparation of Solutions

### Preparation of standard stock solutions (100µg/mL):

10 mg of Guaifenesin is accurately transferred into 100mL volumetric flask some methanol is added, sonicated to dissolve, filtered and made up to the mark with methanol.

### Preparation of standard solution (10µg/mL):

10mL of stock solution is transferred into a 100mL volumetric flask, some methanol is added, sonicated to dissolve, filtered and made up to the mark by methanol.

### Preparation of sample solution:

20 **Mucinex** tablets are grinded into powder and the powder equivalent to 10 mg of Guaifenesin is taken in 100mL volumetric flask, some methanol is added, sonicated to dissolve, degassed, filtered and made up to the mark by the solvent.10mL of the above solution is transferred into a 100mL volumetric flask, some methanol is added, degassed, sonicated to dissolve and made up to the mark by the solvent.

**Method validation:**

The presently developed U.V-Spectrophotometric method is validated for precision, linearity, accuracy, ruggedness and repeatability as per the ICH guidelines. The optical characteristics are given in Table1.

**Table 1. Optical characteristics of Guaifenesin**

| S.no | Parameter | Value |
|---|---|---|
| 1 | Wavelength of Measurement | 224.6 nm |
| 2 | Regression equation | y=0.35x |
| 3 | Slope (S) | 0.035 |
| 4 | Correlation Coefficiet ($r^2$) | 1 |
| 5 | Beer's Law Limits (µg/mL) | 2.5-15 µg/mL |
| 6 | Standard Deviation ($\sigma$) | 0.1937 |
| 7 | LOD (3.3 S/ $\sigma$) | 5.962 |
| 8 | LOQ (10 S/ $\sigma$) | 18.07 |

**Precision:**

Precision is the reproducibility of replicate measurements. Statistically it is expressed as %RSD of the measurements. The precision of the method is evaluated by conducting interday determinations and intraday determinations under identical conditions of the homogeneous solution. The results of interday and intraday precision are given in Table 2.

**Table 2. Results of precision**

| Sl.No. | Level % | Concentration of solution (µg/mL) | Intraday RSD | Interday RSD |
|---|---|---|---|---|
| 1 | 80 | 8 | 0.647 | 0.384 |
| 2 | 100 | 10 | 0.634 | 0.378 |
| 3 | 120 | 12 | 0.598 | 0.343 |

**Linearity:**

Linearity studies are used to know whether the response of the instrument (absorbance) is proportional to the concentration of the analyte or not. Linearity of the method is evaluated by measuring absorbance of six different concentrated solutions of Guaifenesin at 224.6 nm wavelength. By drawing a graph between concentration and absorbance of the solutions, a Calibration graph is constructed, which is shown in Fig.3.

| Conc. (µg) | Absorbance |
|---|---|
| 0.00 | 0.00 |
| 2.50 | 0.091 |
| 5.00 | 0.179 |
| 7.50 | 0.27 |
| 10.00 | 0.358 |
| 12.50 | 0.449 |
| 15.00 | 0.537 |

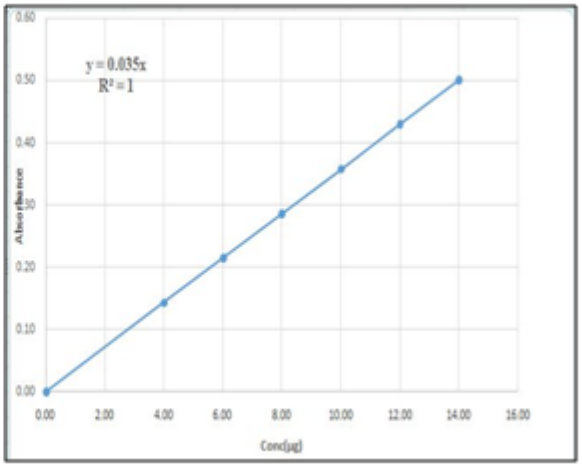


**Figure 3. Linearity plot of Guaifenesin**

The amounts of Guaifenesin present in the linear solutions and their absorbance at 224.6 nm are given in Table 3

**Table 3. The amount of Guaifenesin present in the linear solutions**

| S.No | Level of the solution% | Amount of the drug present (µg/mL) | Absorbance |
|---|---|---|---|
| 1 | 25 | 2.5 | 0.091 |
| 2 | 50 | 5.0 | 0.179 |
| 3 | 75 | 7.5 | 0.270 |
| 4 | 100 | 10.0 | 0.358 |
| 5 | 125 | 12.5 | 0.449 |
| 6 | 150 | 15.0 | 0.537 |

**Accuracy:**

Accuracy gives the difference between the experimental results and true value. The accuracy of the test method is evaluated by the % recovery. The accuracy of the present method is evaluated by the addition of standard API's of Guaifenesin to the pre-analyzed standard solution and subsequent recovery of the total assay present in the solution by the present method. By statistical methods the %RSD is calculated. The lower value of %RSD indicates the accuracy of the method. The results of accuracy studies are given in Table 4.

**Table 4. Results of Accuracy studies**

| Sl.no | Level % | Amount taken µg/mL | Amount of API added µg/mL | Total amount present µg/mL | Amount recovered µg/mL | %Recovery | %RSD |
|---|---|---|---|---|---|---|---|
| 1 | 80 | 10 | 8 | 18 | 17.912 | 99.51 | 0.055 |
| 2 | 100 | 10 | 10 | 20 | 19.861 | 99.31 | 0.285 |
| 3 | 120 | 10 | 12 | 22 | 21.903 | 99.56 | 0.241 |

**Ruggedness:**

It is the degree of reproducibility of the test results obtained by the analysis of the same samples under a variety of conditions such as in different labs/by different analysts/with different instruments etc. The ruggedness of the present method is evaluated by conducting the analysis by different analysts under identical conditions. The results of ruggedness are given in Table 5

**Table 5. Results of Ruggedness**

| Sl.No | Amount taken(µg) | Analyst 1 (µg) | %RSD | Analyst 2 (µg) | %RSD |
|---|---|---|---|---|---|
| 1 | 10 | 9.912 | 0.107 | 9.898 | 0.158 |

**Repeatability**

The repeatability is evaluated by analyzing six solutions of Guaifenesin six times. The results of repeatability are shown in Table 6.

**Table 6. Results of repeatability**

| Sl.No | Amount of drug taken (µg) | Amount found (µg) | %Recovery | %RSD |
|---|---|---|---|---|
| 1 | 10 | 9.94 | 99.4 | 0.647 |

**Determination of assay of the sample:**

The absorbances of six identical sample solutions are measured and by statistical methods the %RSD value is determined. The results of pharmaceutical dosage form **Mucinex** is given in Table 7.

**Table 7. Results of pharmaceutical form Mucinex**

| Sl.No | Amount of Mucinex taken in mg | Amount found in mg | % of Assay |
|---|---|---|---|
| 1 | 10 | 9.94 | 99.40 |

**Students "t"-test and variance ratio test or F-test:**

The % assay determination of the sample by the present method with that of the reference method is compared by "t"-test and F-test and the values are given in the Table 8.

**Table 8. Results of analysis of tablets by the present method and the reference spectrophotometric method –statistical comparison of the results (t and F tests)**

| S.No | Amount of drug in each tablet (mg) | Amount found by the present method (mg) | Amount found by reference method (mg) | $t_{cal}$ | $t_{table}$ | $F_{cal}$ | $F_{table}$ |
|---|---|---|---|---|---|---|---|
| 1 | 10 | 9.94±0.14 | 9.96±0.16 | 1.651 | 3.161 | 2.723 | 6.26 |

## RESULTS AND DISCUSSION

Guaifenesin shows maximum absorbance at 224.6 nm wavelength. In the present U.V-Spectrophotometric method, Guaifenesin obeys Beer`s Law in the concentration range of 2.5-15µg/mL. By conducting interday determinations and intraday determinations under identical conditions, the precision of the method is determined. The % RSD values of interday and intraday precision are less than 2 indicating that the method is precise. In the linearity studies, solutions of 25% to 150% of concentration are prepared and their absorbance is measured at 224.6 nm. A graph is drawn between concentration of Guaifenesin and the absorbance of the solutions. A linear calibration curve is obtained. The solutions follow Beer's law in the concentration range 2.5-15µg/mL and from the slope and standard deviation of the plot, LOD and LOQ are calculated and their values are within the limits. The accuracy is evaluated by the addition of standard API`s of Guaifenesin to pre-analyzed solutions and subsequent recovery studies are made by the present method. The % recoveries are in the limit 100 ± 1 indicating that the method is accurate. The ruggedness is determined by the analysis of the sample under different conditions like different analysts / different instruments etc. In the present method, ruggedness is determined by conducting the analysis by different analysts under the identical conditions. The % RSD of the ruggedness studies is less than 2, hence the method is considered to be rugged. The repeatability is determined by analyzing six solutions of Guaifenesin for six times. In the repeatability studies, % RSD is less than 2 and the method is repeatable. By using the present UV–spectrophotometric method, the assay of the sample is determined, the % of assay of sample is in the limit 100± 1. In the students t-test, $t_{cal}$ is found to be less than $t_{table}$ indicating that the null hypothesis is substantiated i.e. the amounts of the drugs determined by the two methods are considered to be the same with a certain probability. In the variance ratio test or F-test, $F_{cal} < F_{table}$, then the two standard deviations are not significantly different. Hence the method may be used for the rapid, accurate, precise and economic determination of Guaifenesin in bulk and dosage form.

## CONCLUSION

The presently developed U.V-Spectrophotometric method is simple, accurate, precise, economic and sensitive for the determination of Guaifenesin in bulk and dosage form without any

interference from the excipients present. Hence, this method may be used for the routine analysis of Guaifenesin in quality control laboratories.

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