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# DEVELOPMENT OF UV SPECTROSCOPIC METHOD FOR THE DETERMINATION OF GUAIFENESIN IN BULK AND FORMULATION

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**ABSTRACT**

The present research work discusses the development of UV Spectroscopic method for the estimation of Guaifenesin. Simple, specific, accurate and cost effective spectroscopic method has been developed for the estimation of Guaifenesin in bulk as well as formulation. The optimum conditions for the analysis of the drug were established. The maximum wavelength ($\lambda_{max}$) was found to be 240nm. The validation was performed as per ICH guidelines for linearity, accuracy, precision, LOD and LOQ. The method shows high sensitivity with linearity in the range of 1-9 µg/ml and shows a linear relationship between the absorbance and concentration with coefficient of correlation 0.9992. The regression of curve was Y = 0.054 + 0.030. The precision of method was found to be good. The percentage recovery was found to be 99.57 ± 0.38. The optimized showed good reproducibility and recovery with RSD < 2%. The proposed method will be suitable for analysis of Guaifenesin in bulk as well as pharmaceutical formulations in quality control purpose. It is thus concluded that the proposed method is new, simple, cost effective, safe, accurate, precise and environmental friendly.

**Keywords**: Guaifenesin, UV Spectroscopic method, Sensitive, Validation, ICH guidelines.

## INTRODUCTION

Guaifenesin is an expectorant used to reduce chest congestion caused by the common cold, infections, or allergies [1]. Chemically it (*RS*)-3-(2-methoxyphenoxy) propane-1,2 diol **(**Fig 1) [2].

It is available as white or slightly grey crystalline powder which is freely soluble in water and ethanol; soluble in chloroform, glycerol, propylene glycol, n,n dimethylformamide; moderately soluble in benzene; practically insoluble in petroleum ether[3]. Fewer methods have been reported for the quantitative determination of Guaifenesin, which includes UV [4,5], HPLC [6], Voltammetry [7], GC [8], LC-MS [9].

Several methods have been reported in literature for the determination of guaifenesin in the presence of other drugs which includes UV [10-17], HPLC-UV for stability indicating assay, impurities, in human plasma [18-35], HPLC- fluorimetric detection [36-37], HPTLC [38], LC-MS [39-40].

The aim of present work was to develop simple, sensitive, specific spectrophotometric method for detection of Guaifenesin in bulk as well as pharmaceutical formulation.

## MATERIALS AND METHODS

### Equipment and reagents

A Labindia model 3000+ double beam UV-Visible Spectrophotometer with two matched cuvette cells of one cm light path were used for the measurement of absorbance. The Guaifenesin bulk drug was kindly gifted by Shasun Pharmaceuticals Limited, Pondicherry. The pharmaceutical dosage form was procured from market. Distilled water was used for the study.

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**Preparation of standard stock solution**

Accurately weighed 10 mg of Guaifenesin was transferred into 100ml volumetric flask volume was made up to 100 ml with distilled water to get a concentration of 100µg/ml and filtered through the Whatman filter paper no.41.

**Concentration of calibration curve**

Aliquots of standard solution were pipetted out and suitably diluted with distilled water to get final concentration of 1-9 µg/ml. The solution was scanned in spectrum mode of 400 to 200 nm wavelength range and sharp peak obtained at 270 nm shown in Figure.2. Calibration curve was plotted against concentration and absorbance, regression equation was computed. The results tabulated in the table 1.

**Preparation of Sample solution**

Twenty tablets were weighed, average weight determined and crushed into fine powder. An accurately weighed quantity of powder equivalent to 10 mg of Guaifenesin was transferred into 100 ml volumetric flask containing 30 ml distilled Water, shaken manually for 10 min., volume was adjusted to mark with same solvent and filtered through Whatmann filter paper no. 45. An appropriate aliquot was transferred to 10 ml volumetric flask, volume was adjusted to the mark and absorbance was recorded at 270nm.

**Method Validation**

**Accuracy**

Accuracy was carried out at 80 %, 100 % and 120 %of target concentration. From the amount found, percentage recovery was calculated.

**Precision**

Precision of the method was studied by carrying out intraday, interday analysis and expressed as percentage Relative Standard Deviation. For this purpose 1 (LQC), 5 (MQC) and 10 µg/ml (HQC) solutions were prepared and the absorbances of the solutions were measured for six times within the same day and in different days at 270 nm against blank.

**Limit of Detection (LOD) and Limit of Quantization (LOQ)**

LOD and LOQ of the drug were calculated using the following equations according to International Conference on Harmonization (ICH) guidelines

$$LOD = 3.3 \times \sigma/S$$
$$LOQ = 10 \times \sigma/S$$

Where

$\sigma$ = the standard deviation of the response and

S = the slope of the regression equation.

**RESULT AND DISCUSSION**

The proposed method for determination of Guaifenesin in marketed formulation (tablet) showed Sandell's sensitivity of 0.083 µg/cm$^2$/0.001 absorbance units. Linear regression of absorbance on concentration gave the equation y = 0.054x + 0.030 with a regression co-efficient ($R^2$) of 0.9992 and the linearity range was 1-9µg/ml. The higher percentage recovery value (95-105%) indicates that there is no interference of the excipients present in the formulation.

Thus the method is useful for the determination of Guaiphenesin in bulk and pharmaceutical formulations.

**Table 1. Calibration of proposed method**

| S. No. | Conc.(mcg / ml) | Absorbance at 270 nm |
|---|---|---|
| 1 | 1 | 0.012 |
| 2 | 2 | 0.017 |
| 3 | 3 | 0.023 |
| 4 | 4 | 0.029 |
| 5 | 5 | 0.034 |
| 6 | 6 | 0.040 |
| 7 | 7 | 0.047 |
| 8 | 8 | 0.052 |
| 9 | 9 | 0.058 |

**Table 2. Assay of Guaifenesin formulation**

| S. No. | Formulation | Label claim (mg/tab) | Amount found (mg) (n=3) Mean ± SD | Assay | %RSD |
|---|---|---|---|---|---|
| 1 | **Mucinex** | 600 | 585.63±0.055 | 97.63 | 1.088 |

**Table 3. Optimum conditions, Optical characteristics and Statistical data of the Regression equation in UV method**

| Parameter | UV method |
|---|---|
| $\lambda_{max}$ (nm) | 270nm |
| Beer's law limits (mcg / ml) | 1-9 |
| Sandell's sensitivity(mcg / $cm^2$-0.001 absorbance units) | 0.0833 |
| Regression equation (Y*) | y = 0.054x + 0.030 |
| Slope (b) | 0.054 |
| Intercept (a) | 0.030 |
| Correlation coefficient($r^2$) | 0.999 |
| % RSD** | <2 |
| Limit of detection (mcg / ml) | 0.104 |
| Limit of quantitation (mcg / ml) | 0.318 |

*Y=bX + a where X is the concentration of Guaifenesin in mcg/ml and Yis the absorbance at the respective $\lambda_{max.}$ **Average of six determinations

**Table 4. Determination of Accuracy results for Guaifenesin at 270 nm**

| Brand name | % of Spiked sample | Amount of drug added(mcg/ml) | Amount Recovered | % Recovery ± SD** |
|---|---|---|---|---|
| **Mucinex** | 80 | 8 | 17.96 | 99.77±0.14 |
| **Mucinex** | 100 | 10 | 19.96 | 99.83 ± 0.54 |
| **Mucinex** | 120 | 12 | 21.80 | 99.11 ±0.46 |

**Average of six determinations.

**Table 5. Determination of Precision results for Guafenesin at 270 nm**

| Concmcg / ml | Inter-day Absorbance Mean ± SD** | % RSD | Intra-day Absorbance Mean ± SD** | % RSD |
|---|---|---|---|---|
| LQC(1mcg/ml) | 0.012 ± 0.000035 | 0.29 | 0.018 ± 0.000014 | 0.78 |
| MQC(5mcg/ml) | 0.034 ± 0.000019 | 0.556 | 0.037 ± 0.0000208 | 0.562 |
| HQC(9mcg/ml) | 0.058 ± 0.000022 | 0.372 | 0.054 ± 0.000022 | 0.401 |

**Figure 1. Structure of Guaifenesin**

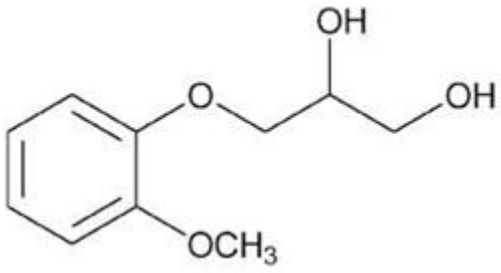



**Figure 2. Calibration curve of Guaifenesin at 270nm**

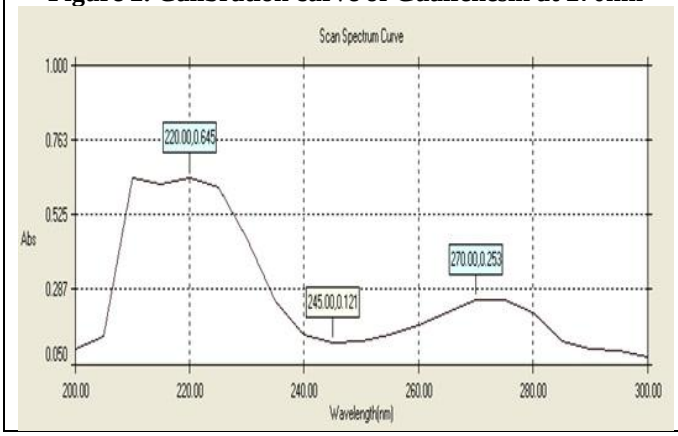
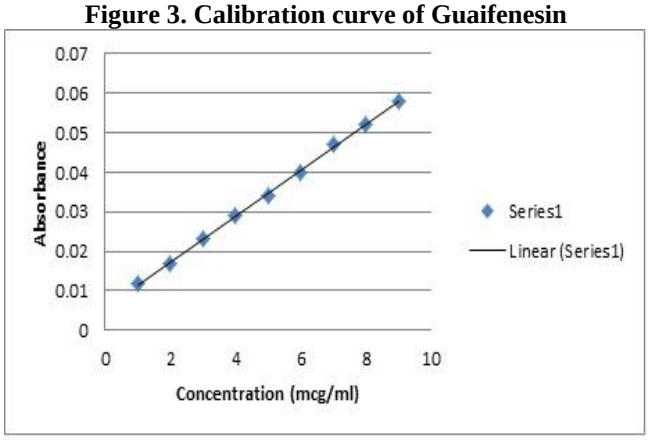



**Figure 3. Calibration curve of Guaifenesin**



## CONCLUSION

A simple, sensitive, accurate and precise UV spectrophotometric method has been developed for quantitative determination of Guaifenesin in bulk and prepared solid dosage form (tablet).

The UV spectrum was scanned between 200 to 400 nm and 270 nm was selected as maximum wavelength for absorption. Beer's law was obeyed in the concentration range of 1 – 9µg/ml. % Recovery was calculated, was found to be 99.11 – 99.77 and the method was successfully applied to the pharmaceutical dosage form containing the Guaifenesin drug without any interference by the excipients.

The method was fast and economical and it was also selective and sensitive for the desirable range. Results of the analysis were validated as per ICH guidelines and by recovery studies.

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