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Mebeverine hydrochloride in pharmaceutical preparation as determined by spectrophotometer using the Ion Association Reaction

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Abstract

A simple, accurate, and sensitive colorimetric method for determining Mebeverine HCL. Pure and pharmaceutical preparations have been developed. The method is based on the formation of an ion-association combination between picric acid and the medication. The range was measured with the maximum absorption at 382.00 nm. With a molar absorptivity of 3.41×10^4 Mol $L^{-1}cm^{-1}$, a relative standard deviation (RSD %) of 0.6430 percent, a mean recovery of 90.776-98.055%, and a correlation value of Between 1.0 and 30.0 µg/ml, the beer's law is observed ($r^2 = 0.990$). This method successfully identified mebeverine HCL in pharmaceutical formulations and bulk.

Keywords: Spectrophotometric Determination; Mebeverine HCL; Picric Acid

1. Introduction

The Mebeverine hydrochloride (MBV) chemical formula is C25 H35 NO 5, and its molecular weight is 466 g/mol. It is a white, crystalline powder. It is nearly insoluble in diethyl ether [1] but easily soluble in water and 96% ethanol. Mebeverine hydrochloride is known by its IUPAC nomenclature 4-(ethyl(1-(4-methoxyphenyl) propan-2-yl) amino) butyl 3,4-dimethoxybenzoate. It works directly on the gastrointestinal system to relax spasms and mostly helps with colonic spasms [2]. To treat gastrointestinal spasmodic, including irritable bowel syndrome, Mebeverine is frequently utilized as a relaxant [3].

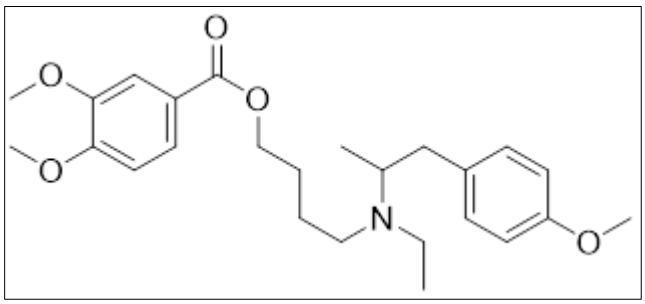

Figure 1 Chemical Structure of Mebeverine Hydrochloride

Numerous analytical techniques, such as spectrophotometry [4–10], Spectroscopy of construction [11], and high-performance liquid chromatography [12–19]. Ion-specific electrodes [20], and electrodes made of carbon paste [21] have been found through a literature search for the quantification of MBV pharmaceutical dosage forms. Establishing a

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simple, quick, precise, and accurate method for determining mebeverine HCl in pharmaceutical formulations and bulk is the aim of the study.

2. Material and reagent

- 0.01 grams of MBV were dissolved in DI chloro methane (DCM) to create a stock solution.
- Picric acid (2.150×10^{-4}M) was prepared by dissolving (0.2 gm) in 50 ml DCM in a volumetric flask 50.

2.1. The suggested course of action

Fill a volumetric flask with 0.1-3 ml of the standard solution MBV. Fill each flask with 2 ml of picric acid solution, then stir and dilute with DI chloro methane to volume. For half an hour, leave the solution in the dark. Compare the absorbance at 382 nm to the blank that was prepared at the same time.

2.2. Procedure for pharmaceutical preparations

The tablets were finely pulverized and weighed. A 100 ml volumetric flask was filled with precisely weighed portions of powder equal to 100 mg of MBV. The powder was dissolved and filled to the mark with DI chloro methane to achieve 100 mg/ml. The mixture was filtered through after being swirled for ten minutes on 0.5µ filter paper and then filled to the mark with the same solvent.

3. Results and discussion

The MBV solution was scanned using a U.V. spectrophotometer in the 200–400 nm range. The results showed that the MBV had the highest absorbance at 382 nm, which, as illustrated in Fig (2), was used as the precise wavelength to calculate the drag.

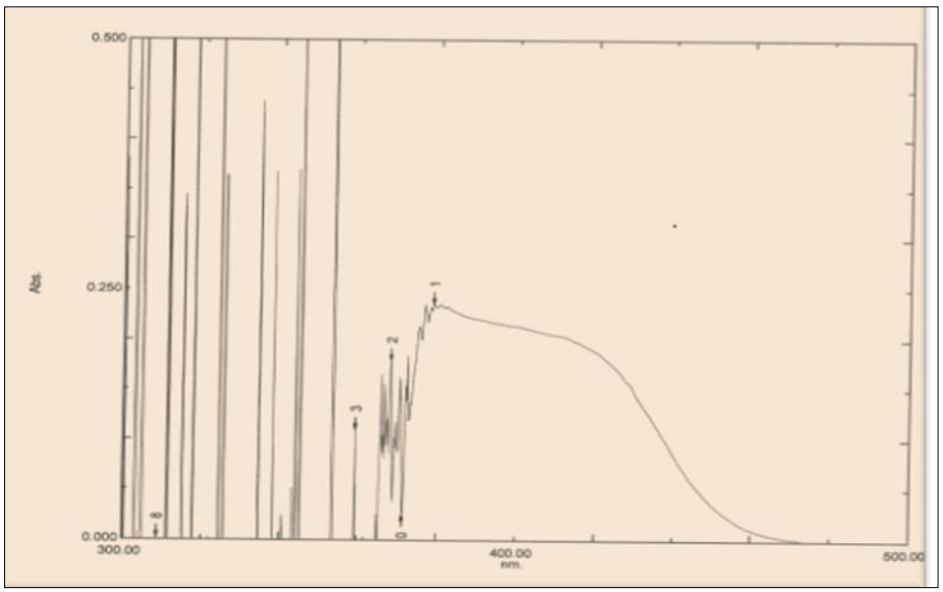

Figure 2 Absorption spectra of picric acid (1.754×10^{-2} M) and the colorful compound (2.150×10^{-5} M) 0f MBV

3.1. Enhancement of the experimental environment

The circumstances of the reaction were adjusted, and several factors influencing the intensity of the complex's absorption were investigated.

3.2. Impact of the concentration in picric acid

Various amounts ranging from 1 to 5 milliliters were extracted from the legend. Volume 5 produced extremely strong absorption, as seen in Fig (3), while at max 382 nm, volume 2ml yielded the highest absorption intensity.

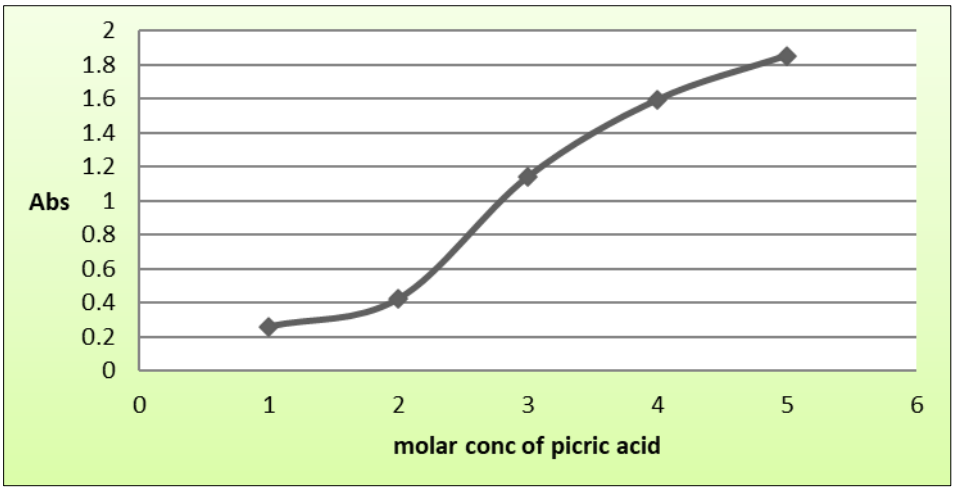

Figure 3 Impact of varying 1.754x10-2 M picric acid volumes on the complex's absorption between picric acid and MBV

3.2.1. Time's impact

Following a reaction between MBV and picric acid, the color intensity achieved its maximum absorption for 30 minutes. Consequently, thirty minutes of development time was chosen for later usage. The results are shown in figure (4):

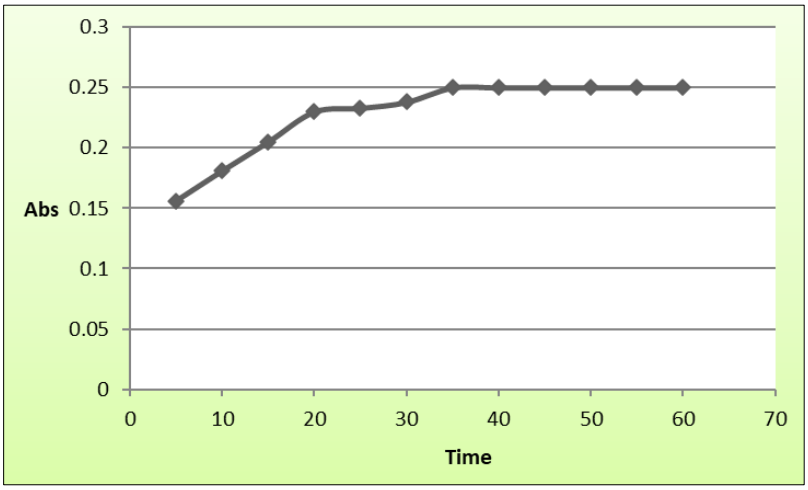

Figure 4 Impact of Duration on MBV Absorption

3.2.2. Selecting an organic solvent

To determine which organic solvent would provide a blank with low absorption and high absorbance, Tests were carried out with a range of organic solvents, including dichloroethane, dichloromethane, chloroform, acetone, and ether. Dichloromethane provided the highest absorbance and was chosen above other solvents due to its selectivity.

3.3. The impact About temperature

Since DCM, the solvent used has a boiling point, the impact of temperature on complex stability was not investigated. Below 40 °C.

3.3.1. Graph of calibration

Under optimal conditions, a linear calibration graph covering the concentration range of 1–30 µg/ml was generated for the determination of MBV. The linear regression equation is Y=0.020X+0.178, with a correlation coefficient of 0.990, as illustrated in Figure (5).

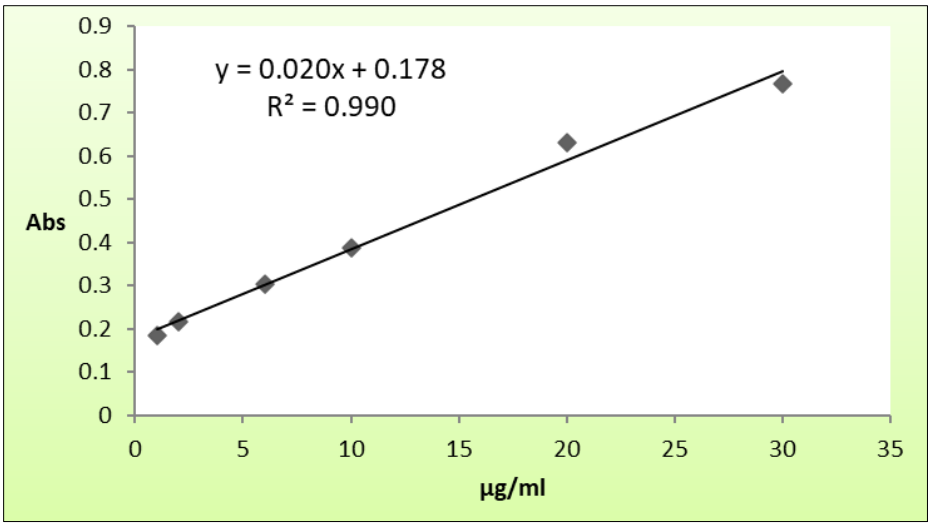

Figure 5 Calibration Graph for MBV Calculation

3.3.2. Character of the dye product

Using the mole ratio and jobs method Mebeverine and picric acid interaction stoichiometry was investigated. The results obtained indicate that the drug-ligand reaction follows the % 1:2 drugs/reagent as shown in Fig. (6) and f.7. Additionally, this confirmed that the response was followed as the course in Figure 6.

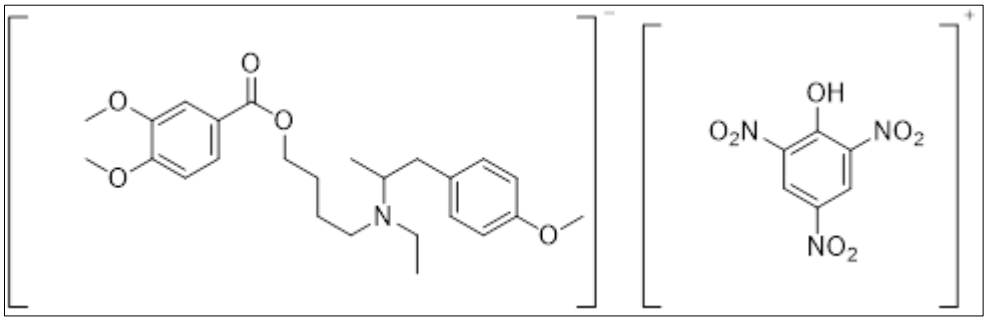

Figure 6 Hypothesized MBV-formation mechanism

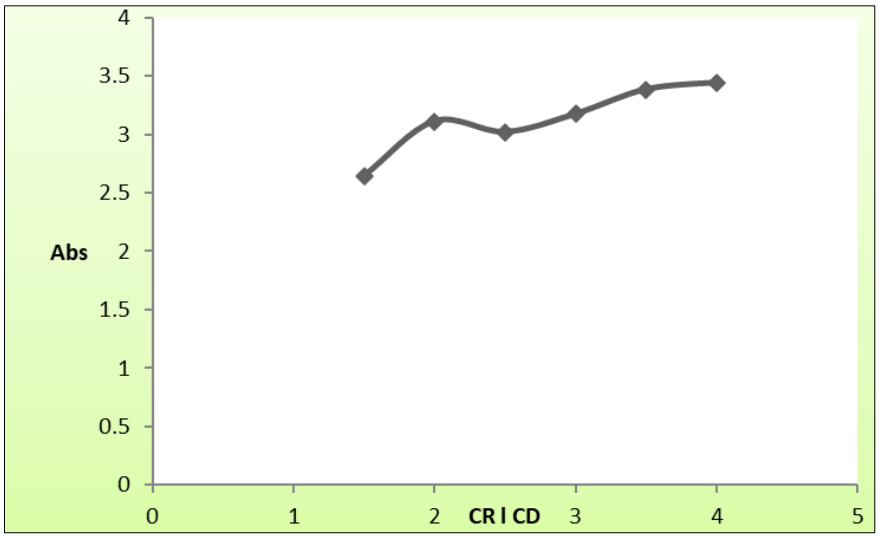

Figure 7 mole fraction of drug

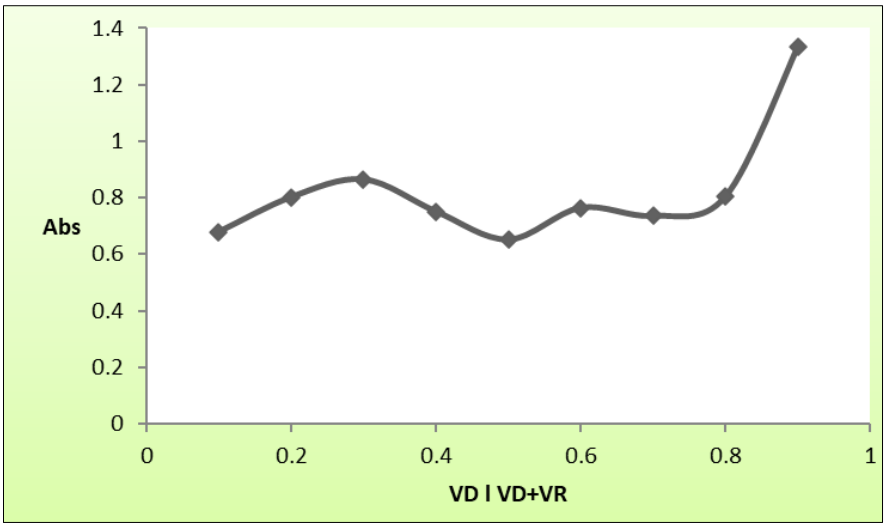

Figure 8 represents the mole ratio

3.3.3. Stability of the ion-pair complexes

It was determined how stable the combination that developed between MBV and picric acid was. Even so, it took only 30 minutes and 20 degrees Celsius to get consistent observing readings. For at least two hours, the generated compound remained stable with no change in absorbance. The stability of the developing complex was corroborated by the conditional constant, which was determined to be 3.949×10^3 by the literature [22].

3.4. Assessment of the suggested approach

3.4.1. Preciseness and accuracy

Based on recovery values ranging from 94.85 to 99.31%, the evaluation of the three concentration levels showed that the recommended method was accurate. Furthermore, the process appeared to be highly exact based on the low R.S.D.% values (0.4076-2.949) %.

Table 1 RSD and recovery values for the drug

N	Con. In µg/ml	Found	R.S.D %	Recovery %
1	2.00	1.9646	2.949	98.2316
2	10.00	9.9317	2.006	99.3198
3	30.00	28.4559	0.4076	94.8540

3.4.2. Studies of interference

According to the results, using different drug concentrations up to (2,10,20) µg/ml, 100 µg/ml of each excipient (starch, glucose, magnesium, stearate, lactose, talk, and acacia) did not interfere with the measurement of MBV.

Table 2 The impact of the interfering elements found in pharmaceutical formulations of the medication is displayed.

Concentration of MBV. µg/ml	Mean Recovery (%)
2	110.1941
10	97.2815
30	94.0776

3.4.3. Detection limits and quantification

The quantification limits (LOQ) and detection (LOD) were unquestionably set at Where K is the value of LOD = 3 SD/K and LOQ = 10 SD/K, calibration graph's slop and The standard deviation of five replicate determination readings obtained under the same conditions but without the medication is known as SD. [22] . The LOD and LOQ were determined to be (0.7718) and (2.5728), respectively, based on these two factors.

3.5. Application of analysis

The results of analyzing MBV in both its pure form and its pharmaceutical formulations using the proposed method demonstrate that it was a precise and accurate technique. Good precision and consistency were indicated by the low relative standard deviation (R.S.D%). The mean percent recoveries, which ranged from 97.18 to 99.55, demonstrated the accuracy of the proposed approach.

Table 3 The outcomes were attained by using the suggested approach

Company	Claimed/ mg	Found	Recovery (%)	R.S.D%
Duspatalin	135.00	131.21	97.180	1.3212
EVACOL	135.00	133.52	98.880	1.4901
MEVA	135.00	134.41	99.550	1.3801

4. Conclusion

The proposed method demonstrates high accuracy and sensitivity in estimating MBV in pharmaceutical formulations and bulk materials. The proposed method offers advantages such as the rapid assessment of the drug's purity and medicinal formulation, along with its simplicity and the absence of heating at 25 °C. The method's extensive linearity rendered it an advantageous option for pharmaceutical manufacturers. Since the technique did not impede the analysis, it was advantageous for regular analysis and quality control tests of the drug in tablets and raw materials.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed

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