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*Article*

# Mebeverine Hydrochloride in Pharmaceutical Preparation as Determined by Spectrophotometer Using the Ion Association Reaction

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**Abstract:** This study aims to develop a simple, accurate, and sensitive colorimetric method for determining Mebeverine Hydrochloride (MBV) in its pure form and pharmaceutical preparations. The method relies on the formation of an ion-association complex between Mebeverine and picric acid, with maximum absorption measured at 382 nm. Using spectrophotometry, the method demonstrates high sensitivity, with a molar absorptivity of $3.41\times10^4$ L $mol^{-1}$ $cm^{-1}$ and a linear calibration range of 1–30 µg/ml ($R^2 = 0.990$). The experimental procedure optimizes factors such as picric acid concentration, reaction time, and solvent selection to enhance accuracy and reproducibility. Validation of the method shows high precision (RSD: 0.4076–2.949%) and recovery rates (94.85–99.31%). Interference studies confirm that common excipients do not affect the analysis. The results indicate that the proposed method is effective for routine quality control of MBV in pharmaceutical formulations, offering simplicity, stability, and reliability in drug quantification.

**Keywords:** Spectrophotometric Analysis, Mebeverine Hydrochloride Determination, Ion-Association Complex



## 1. Introduction

The chemical formula of mebeverine hydrochloride (MBV) is C25 H35 NO 5, and its molecular weight is 466 g/mol. It is a white, crystalline powder. It is nearly insoluble in diethyether (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). In order to treat gastrointestinal spasmodics, including irritable bowel syndrome, mebeverine is frequently utilized as a relaxan (3).

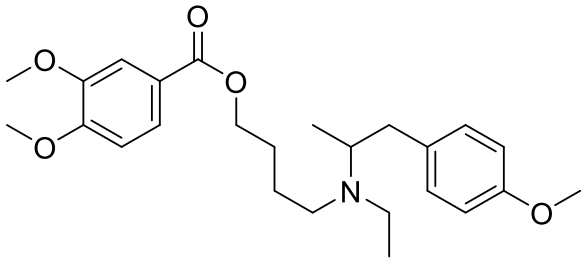


Fig 1: Chemical Structure of Mebeverine Hydrochloride.

Numerous analytical techniques, such as spectrophotometry [4–10], Spectroscopy of construction [11], high-performance liquid chromatography [12–19]. Ion-specific electrode [20], With electrodes made of carbon paste [21] have been found through a literature search for the quantification of MBV pharmaceutical dosage forms. Establishing a simple, quick, precise, and accurate method for determining mebeverine HCl in pharmaceutical formulations and bulk is the aim of the study.

## 2. Materials and Methods

**Material & reagent:**

a. 0.01 grams of MBV were dissolved in DI chloro methane (DCM) to create a stock solution.

b. picric acid (2.150×10-4M) was prepared by dissolving (0.2 gm) in 50 ml DCM in volumetric flask 50ml.

**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.

**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 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 wave length to calculate the drag.

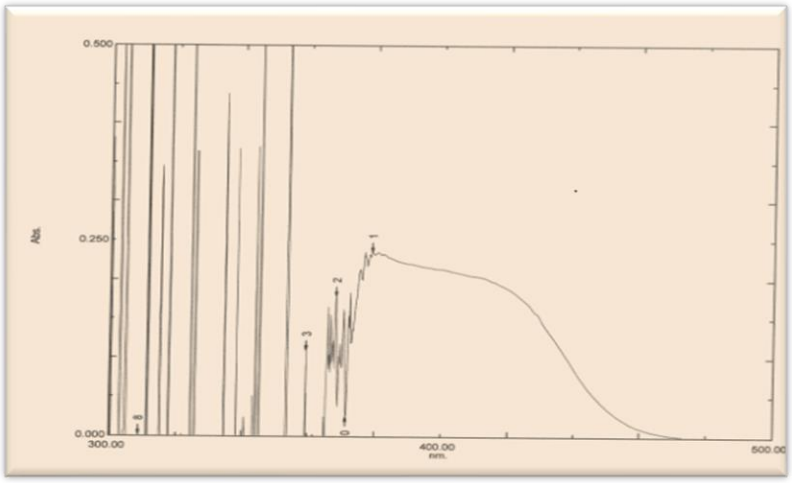



**Fig 2:** Absorption spectra of picric acid ($1.754\times10^{-2}$ M) and the colorful compound ($2.150\times10^{-5}$ M) 0f MBV.

**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.

**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.

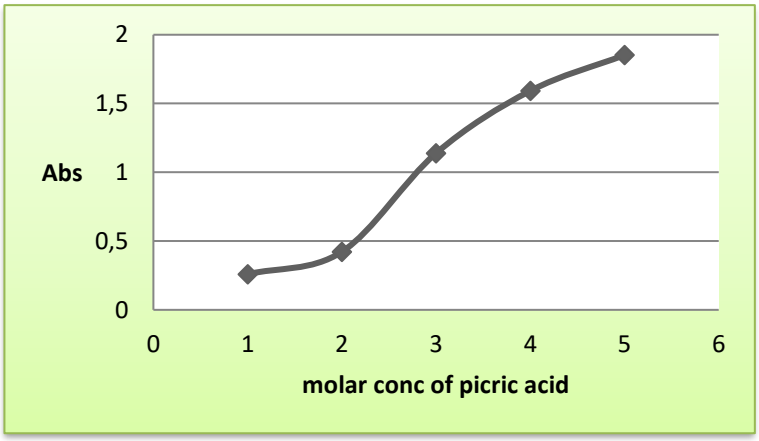



**Fig 3:** Impact of varying 1.754x10$^{-2}$ M picric acid volumes on the complex's absorption between picric acid and MBV.

**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):

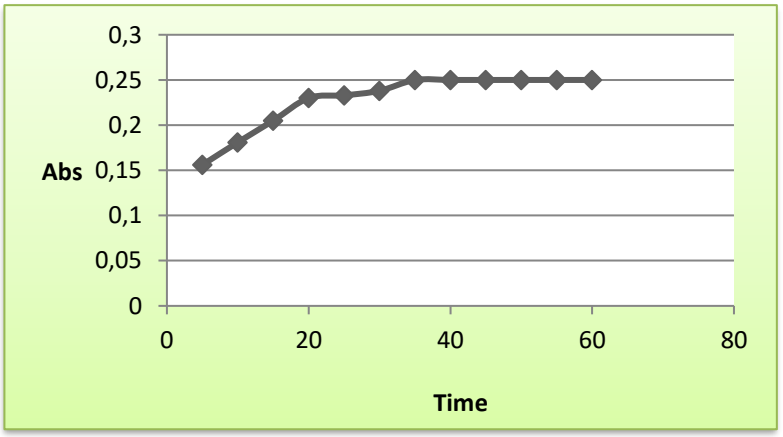



**Fig 4**: Impact of Duration on MBV Absorption

**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.

**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.

**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 (6).

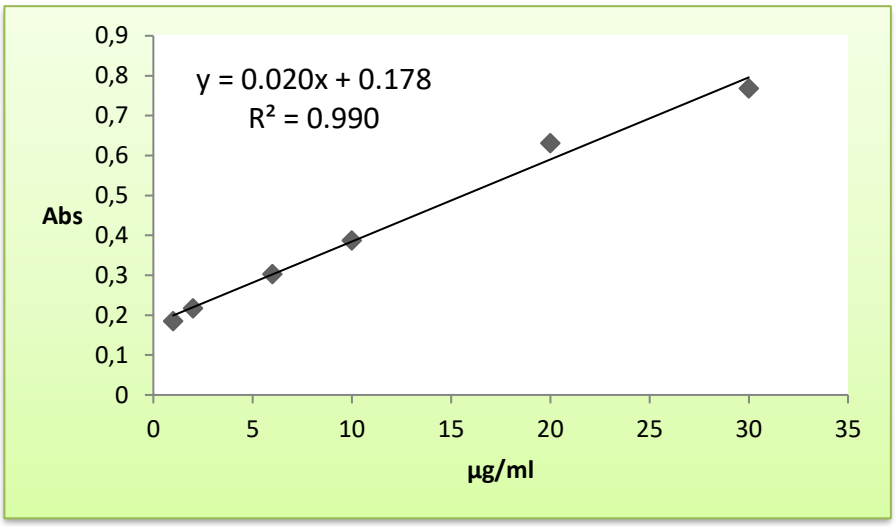
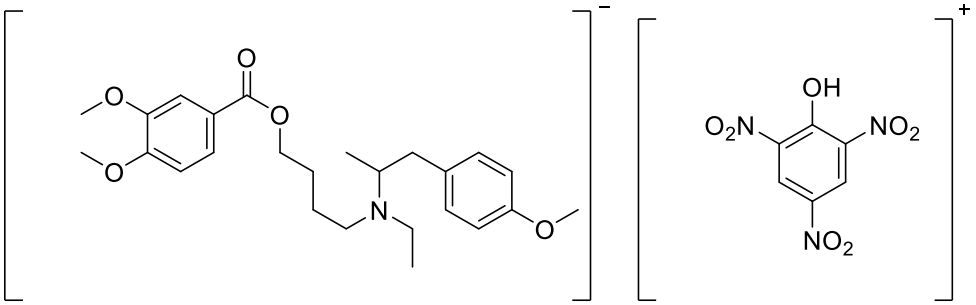


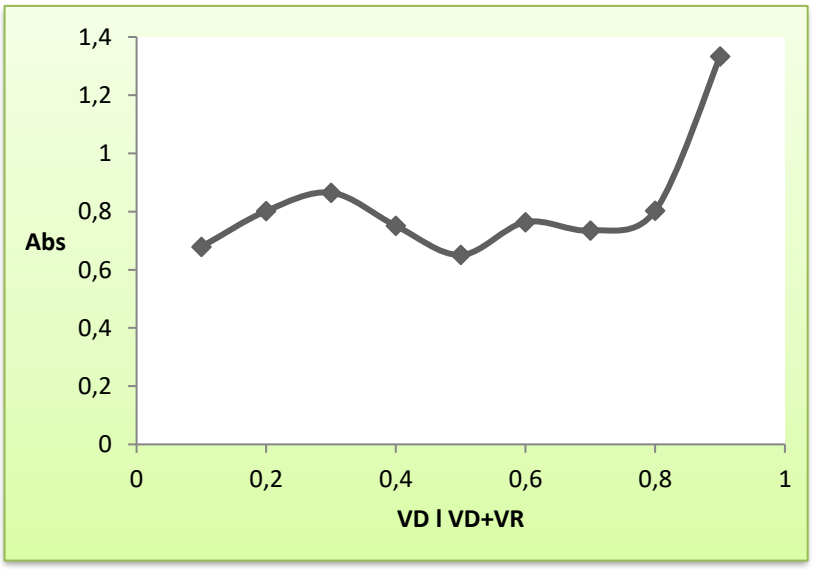

**Fig.5**: Calibration Graph for MBV Calculation.

**Character of the dye product:**

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




**Scheme 1.** Hypothesized MBV-formation mechanism.



**(6)** mole fraction of drug

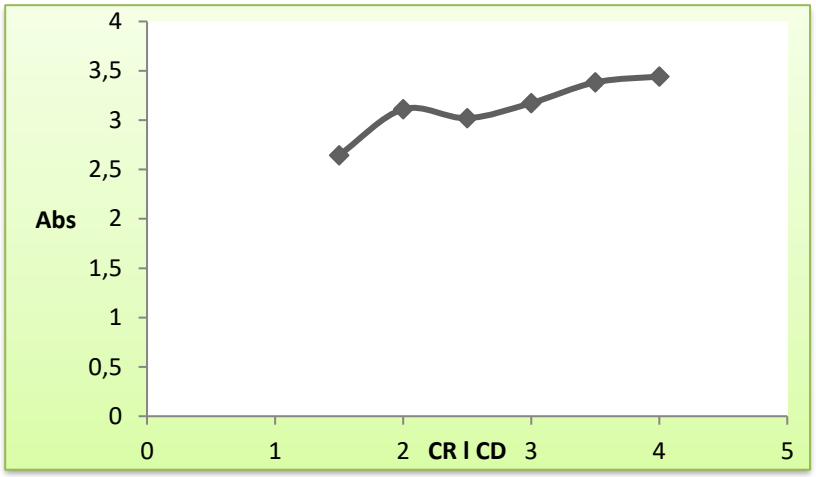



Fig (7) represented the mole ratio.

**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 the 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 $3.949\times10^3$ in accordance with literature [22].

**Assessment of the suggested approach:**

**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 |

**Studies of interference:**

According to the results, using with different drug concentrations up to (2,10,20) µg/ml, 100 µg/ml of each excipient (starch, glucose, magnesium, stearate, lactose, talk, and aacia) 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** |

**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.

**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 (2).** The outcomes 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** |

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 manufacture. 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.

## 4. Conclusion

The proposed spectrophotometric method for the determination of Mebeverine Hydrochloride (MBV) demonstrates high accuracy, precision, and reliability, making it an effective tool for routine analysis and quality control of pharmaceutical formulations and bulk materials. By forming an ion-association complex between MBV and picric acid, the method achieves maximum absorption at 382 nm, providing a sensitive and efficient approach to MBV quantification.

The study successfully optimized experimental conditions, including picric acid concentration, reaction time, and solvent selection, to enhance the method's performance. Validation results indicate strong linearity across a concentration range of 1–30 μg/ml ($R^2 = 0.990$), low relative standard deviations (RSD: 0.4076–2.949%), and recovery rates ranging from 94.85% to 99.31%. Interference studies confirm that the presence of common excipients does not affect the method's accuracy.

The method's simplicity, cost-effectiveness, and stability make it advantageous for pharmaceutical manufacturing and quality control processes. Its ability to provide rapid and reproducible results without requiring complex equipment or conditions further enhances its utility.

Overall, the spectrophotometric method offers a reliable means of assessing MBV content, ensuring the quality and consistency of pharmaceutical products. This approach can serve as a benchmark for developing similar analytical techniques for other pharmaceutical compounds.

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