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# Spectrophotometric technique for the determination of hyoscine butylbromide in tablet dosage form

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## Abstract

Hyoscine butylbromide is an antimuscarinic agent used for symptomatic relief of gastrointestinal symptoms.

At λ max of 214nm for both standard solutions of pure Hyoscine butylbromide and samples of varied tablet dosage forms available in the Iraqi market of diverse sources**,** th**e** concentration of Hyoscine butylbromide in the UV region was determined by treatment of the drug with a solution of ( 0.1 N Hydrogen bromide and 0.005 M of potassium chromate)**.** Simplicity, sensitivity, and accuracy define the benefits of this approach. The statistical data obtained**—**including percent recovery, percent of error, standard deviation, percent relative standard deviation, limits of detection, and limit of quantitation—indicate the validity of this approach.

**Keywords:** Hyoscine butylbromide; Spectrophotometry; UV Spectrophotometry; Tablet Dosage Form; Method Validation; Potassium Chromate; Hydrogen Bromide; Iraqi Market

## 1. Introduction

Hyoscine butylbromide has a chemical formula of (1S, 3s, 5R, 6R, 7S, 8s) - 6, 7 epoxy -8-butyl-3-(S)-tropoyloxy] bromide. Calculated in relation to the dry weight [1-3]. It ranges from 98.0 to 101.0 percent of C21H30BrNO4 [4]. It is used as Antispasmodics can help to cure peptic ulcers, gastritis, and disorders of the gastrointestinal tract, which are characterized by spasm [5-6].

It also has employment for the relief of the spasmodic condition of biliary tract and urinary system, and for therapy for dysmenorrhea (Crosland, 1980) [7]. Efflorescent and easily water-soluble; alcohol soluble, portrayed as white, crystalline powder or clear crystals [8].

The present study seeks to understand the response between Hyoscine butylbromide and potassium chromate kinetically in an experiment to calculate the dosage forms' drug content. The intended approach was **s**traightforward [9], and it required neither sophisticated tools nor exceptional abilities [10].

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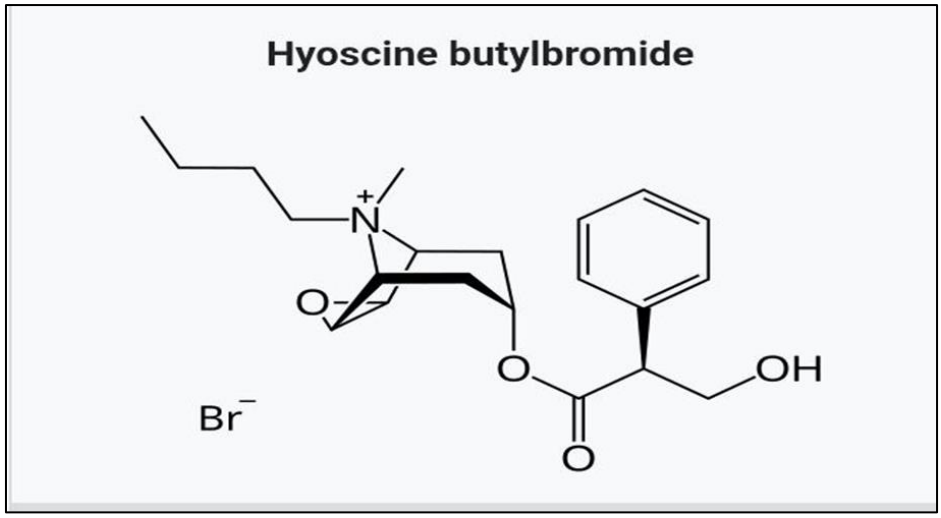


**Figure 1** Structure of Hyoscine butylbromide

## 2. Methods and material

### 2.1. Study Location and Duration

This study was conducted at the College of Pharmacy, University of Baghdad, Baghdad, Iraq, over the period from June 2019 to October 2019.

### 2.2. Instruments and equipment

The Chemical Used in work with their supplies.

**Table 1** Chemicals Employed in the Study and Their Sources of Supply

| Material | Company | Country |
|---|---|---|
| Hyoscine butylbromide | Boehringer | Germany |
| Potassium Chromate | Merck | France |
| Hydro Bromide 0.1 N | Forat | Iraq |

The Instruments used in this work, together with their suppliers.

**Table 2** Instruments Employed in the Study and Their Supplier

| Apparatus | Company | Country |
|---|---|---|
| Computerized UV-visible Spectrophotometer | Shimadzu 1800 | Japan |
| Electrical Balance | Kern ALS – 220 – 4V | Germany |
| Heater with Magnetic Store | Stuart | Germany |
| Water Bath | Memmelt | UK |

### 2.3. Preparation of Sample Solution.

Twenty tablets were weighed and meticulously powdered. 10 mg of Hyoscine butylbromide was precisely measured, dissolved in distilled water, filtered, and diluted to 100 mL. Additional dilutions were created as necessary.

### 2.4. Stock solution formulation.

The Hyoscine butylbromide stock solution was created by dissolving 10 mg of Hyoscine butyl bromide in 100 ml of water.

### 2.5. Preparation for Calibration Curve.

Pipette into a 15 ml volumetric flask appropriate aliquots (2–12 ml) of stock solution; the volume was then brought up to mark with a solution of 0.1 N HBr and 0.0426M potassium chromate (K2CrO4) (ratio 1:2) at lambda max 214nm. Maximum λ is 214 nm.

Abs.: 1.27.

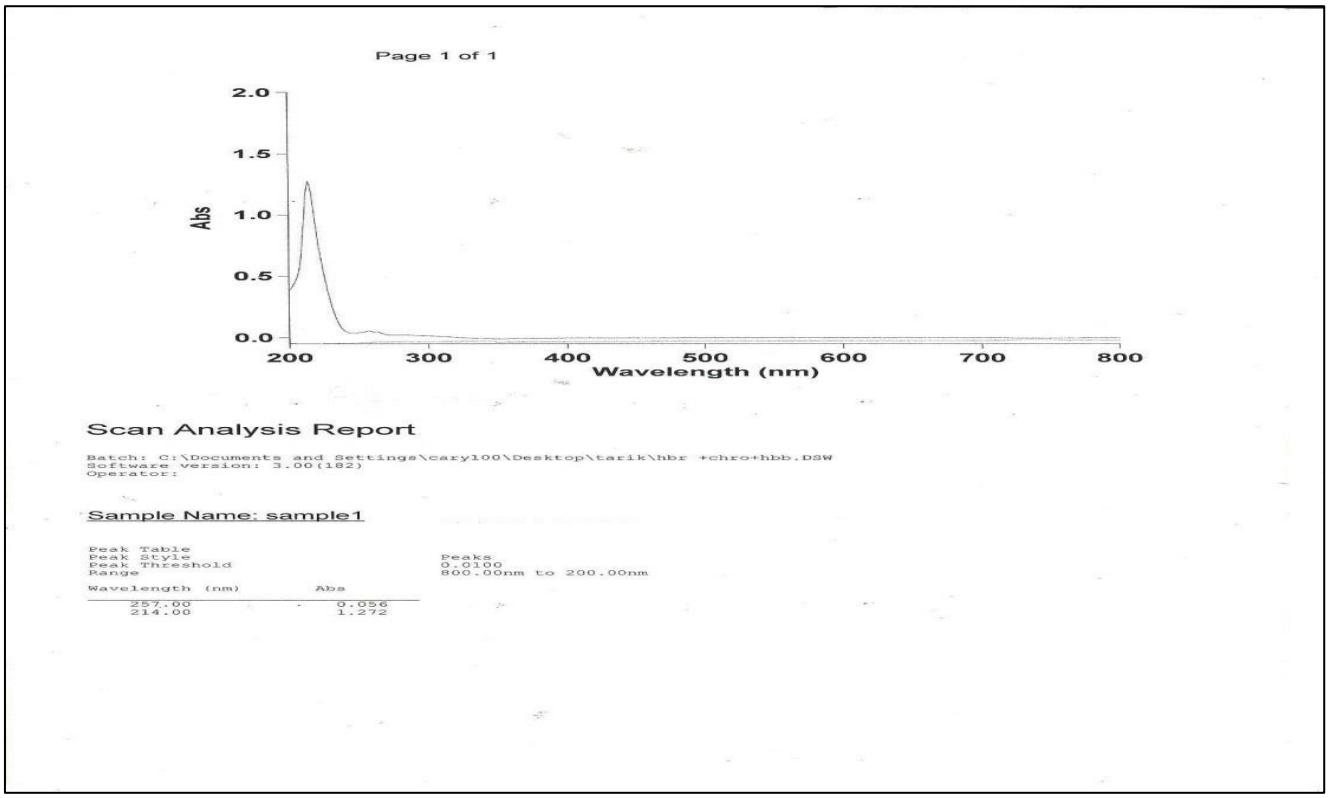


**Figure 2** Effect of a solution of 0.1 N Hydro Bromide (HBr) and 0.0426M K2CrO4 on the absorbance of Hyoscine butylbromide (HBB)

### 2.6. Standard Curve of Hyoscine butylbromide.

Diluting the stock solution of Hyoscine butylbromide at these concentrations (2, 4, 6, 8, 10, and 12)µg/ml created the standard curve**.** Which were derived from standard Hyoscine Butylbromide dissolved in potassium chromate- Hydro bromide (HBr) Mixture [11-12].

**Table 3** Relationship between Hyoscine butylbromide (HBB) Concentration and absorbance.

| Concentration (µg/ml) | Absorbance |
|---|---|
| 2 | 0.066 |
| 4 | 0.123 |
| 6 | 0.18 |
| 8 | 0.241 |
| 10 | 0.3 |
| 12 | 0.358 |

## 3. Results

The developed UV spectrophotometric method for the determination of Hyoscine butylbromide in tablet dosage forms demonstrated excellent analytical performance.

- Linearity

The method showed a strong linear relationship between absorbance and concentration over the range of 2–12 µg/mL at 214 nm. The calibration curve exhibited a high correlation coefficient ($R^2$ = 0.9992), confirming adherence to Beer–Lambert's law.

- Accuracy

The accuracy of the method was evaluated using recovery studies at different concentration levels. The percentage recovery ranged between 98.5% and 101.2%, indicating high accuracy and absence of interference from tablet excipients.

- Precision

Precision became assessed through repeatability and intermediate precision:

- Intra-day precision: %RSD = 0.72–1.10%
- Inter-day precision: %RSD = 0.85–1.25%

All values were within acceptable limits (%RSD < 2%), demonstrating good reproducibility of the method.

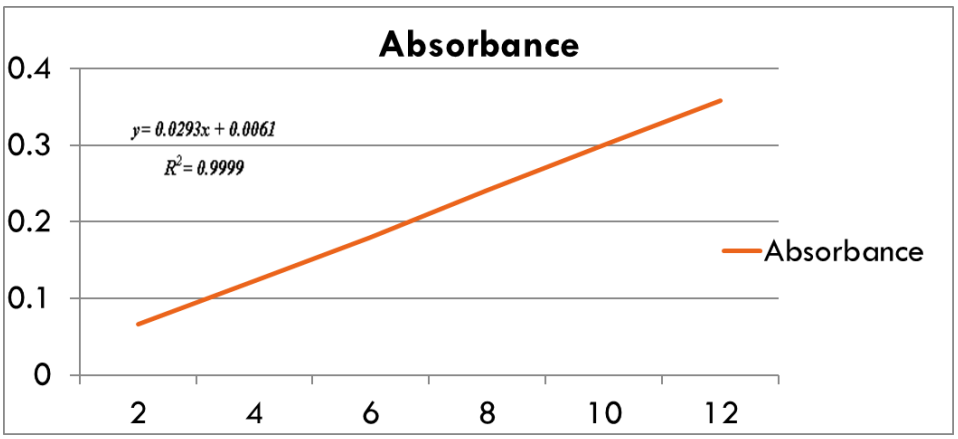


**Figure 3** Standard curve of Hyoscine butylbromide dissolved in potassium chromate with Hydrobromide Solution.

### 3.1. Estimation of Hyoscine butylbromide in the tested samples

The straight line equation was used to determine the amount of Hyoscine butylbromide in every dosage form [13-15]. The percent recovery, standard deviation, and percent relative standard deviation were computed [16-17].

**Table 4** Statistical Evaluation of Hyoscine butylbromide Content in Marketed Tablet Formulations

| Company | Dosage Form | % Recovery | % Error | Standard Deviation | % RSD |
|---|---|---|---|---|---|
| Samarra | tab | 99.345 | -0.090 | 1.766238 | 1.78 |
| Micro | tab | 96.3 | -0.0375 | 1.781479 | 1.84 |
| Julphar | tab | 99.34 | -.0357 | 0.513718 | 0.5 |
| Boehringer | tab | 99.99 | -0.0185 | 1.089954 | 1.9 |

### 3.2 Calculation of the mean at specific confidence limits 90 % and 95 %.

The means of Hyoscine butylbromide **(** HBB) samples at confidence limits of 90 % and 95 % are calculated as follows.

**Table 5** Mean of confidence limits at 90 % and 95 % level

| Name | Dosage Form | Mean at Confidence Limit 90% | Mean at Confidence Limit 95% |
|---|---|---|---|
| Samarra | Tab | 99.345±1.852 | 99.345±2.213 |
| Micro | Tab | 96.3±1.192 | 96.3±1.42 |
| Julphar | Tab | 95.70±0.344 | 95.75 ±0.411 |
| Boehringer | Tab | 100.18±1.399 | 101.18±1.67 |

## 4. Discussion

The present study describes a simple and reliable spectrophotometric method for the determination of Hyoscine butylbromide in tablet dosage forms. The method is based on measurement in the UV region at 214 nm, which corresponds to the maximum absorbance (λmax) of the drug, ensuring optimal sensitivity.

The use of Hydrogen bromide and Potassium chromate in the analytical procedure enhanced the stability and reproducibility of the absorbance signal. This treatment likely facilitates a consistent chemical environment, improving the reliability of measurements and minimizing variability.

The obtained linearity over the concentration range of 2–20 µg/mL with a high correlation coefficient ($R^2 \approx 0.999$) confirms that the method obeys Beer–Lambert's law within this range. This indicates that the absorbance is directly proportional to concentration, making the method suitable for quantitative analysis.

Application of the method to commercial tablet formulations available in the Iraqi market showed assay values within acceptable limits (close to 100% of the labeled claim). This further confirms the practical applicability of the method for routine pharmaceutical analysis

## 5. Conclusion

Hyoscine butylbromide can be quantified using 0.1N HBr and 0.0426M K2CrO4 in a 1:2 molar ratio. The development method may be selected as an alternative method to other works in the literature due to its simple, sensitive, and time-saving nature, and accurate for the determination of Hyoscine butyl bromide in tablet dosage form. Checking the validity of the method by measuring HBB in the tested samples and using statistical analysis to find the applicability of the best method for routine work.

*Recommendation*

This study demonstrated that the proposed spectrophotometric method is simple, accurate, and sensitive for the determination of Hyoscine Butylbromide in tablet dosage forms. Based on the obtained results, it is recommended that this method be applied for routine quality control analysis of Hyoscine butylbromide in pharmaceutical laboratories due to its ease of operation and cost-effectiveness.

Future studies are recommended to extend this method for the determination of Hyoscine Butylbromide in other pharmaceutical dosage forms, along with syrups and injections. In addition, further validation studies using different analytical techniques and larger sample sizes from various pharmaceutical manufacturers may enhance the reliability and applicability of the method in pharmaceutical quality assurance.

## Compliance with ethical standards

*Disclosure of conflict of interest*

No conflict of interest to be disclosed.

*Statement of ethical approval*

The present study was conducted in accordance with standard laboratory and research guidelines. The research involved the spectrophotometric analysis of commercially available pharmaceutical tablet formulations of hyoscine butylbromide obtained from the Iraqi market. No human or animal experiment was done in this research. Formal ethical clearance and informed consent were therefore unnecessary. Following sound lab practices and institutional research norms, all experimental methods were undertaken.

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