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ASSESSMENT OF PERCENTAGE RECOVERY STUDY OF TETRABENAZINE AND ITS PHARMACEUTICAL DOSAGE FORMS BY UV

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ABSTRACT

Spectroscopy is a fundamental analytical technique that examines the interaction between electromagnetic radiation and matter and is extensively applied in pharmaceutical analysis for both qualitative and quantitative purposes. Among various spectroscopic techniques, ultraviolet–visible (UV–Vis) spectroscopy is widely employed due to its simplicity, rapid analysis, accuracy, and cost-effectiveness. The present study was aimed at the development and validation of a simple, precise, and economical UV spectrophotometric method for the quantitative estimation and percentage recovery assessment of tetrabenazine in pharmaceutical dosage forms. Tetrabenazine, a vesicular monoamine transporter-2 (VMAT2) inhibitor used in the treatment of chorea associated with Huntington's disease, requires accurate dosage determination due to its narrow therapeutic index. Pre-formulation studies were carried out to evaluate the physicochemical properties of the drug, including organoleptic characteristics, melting point, solubility, pH, and compatibility. Tetrabenazine exhibited good solubility in ethanol, which was selected as the analytical solvent. UV spectroscopic analysis revealed a maximum absorbance (λmax) at 350 nm. The method demonstrated excellent linearity in the concentration range of 20–120 µg/mL with a correlation coefficient (R^2) of 0.9999, confirming compliance with Beer–Lambert's law. The developed method was validated in accordance with ICH guidelines for specificity, linearity, accuracy, precision, ruggedness, robustness, limit of detection, and limit of quantitation. The percentage recovery of approximately 98% indicated good accuracy, while %RSD values below 2% confirmed precision and reproducibility. The validated UV spectrophotometric method is reliable, rapid, and suitable for routine quality control analysis of tetrabenazine in bulk drug and tablet dosage forms.

KEYWORDS: UV–Visible spectroscopy; Tetrabenazine; Method validation; Pharmaceutical analysis; Beer–Lambert law; Quality control.

INTRODUCTION

Spectroscopy is an analytical technique that studies the interaction between electromagnetic radiation and matter, primarily through absorption, emission, or scattering processes as a function of wavelength or energy. Initially focused on light–matter interactions, spectroscopy has expanded to include particle interactions and has played a fundamental role in the development of key scientific theories such as quantum mechanics and quantum electrodynamics (Sharma, 2007). Today, spectroscopic techniques are extensively applied in chemistry, pharmaceuticals, food analysis, and material sciences for qualitative and quantitative analysis.

Among various spectroscopic methods, **ultraviolet–visible (UV–Vis) spectroscopy** is one of the most widely used analytical tools in modern laboratories due to its simplicity, speed, accuracy, and cost-effectiveness. UV–Vis spectroscopy is an absorption-based technique that operates in the wavelength range of approximately 190–800 nm. It involves the absorption of ultraviolet or visible radiation by molecules, resulting in the excitation of electrons from lower to higher energy states (Picollo et al., 2019). The resulting absorption spectrum is

characteristic of the molecular structure and electronic configuration of the analyte.

The fundamental principle governing UV–Vis spectroscopy is the **Beer–Lambert law**, which states that the absorbance of a solution is directly proportional to the concentration of the absorbing species and the path length of the sample cell. This relationship allows for accurate quantitative analysis through calibration curves, provided the system follows linearity within a defined concentration range (Wittung et al., 1994). Deviations from Beer's law may arise due to instrumental limitations, chemical interactions, or high analyte concentrations (Ansell et al., 1995).

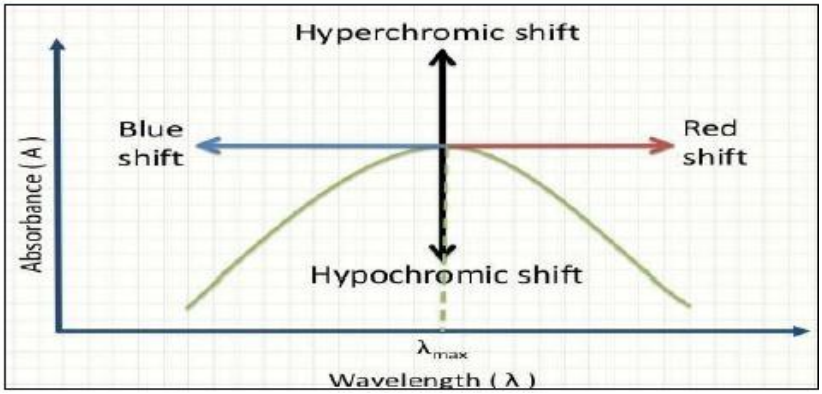

Figure 1: Shifting of absorption bond.

UV–Vis absorption occurs due to various **electronic transitions**, including σ→σ*, n→σ*, π→π*, and n→π* transitions, depending on the nature of chemical bonds and functional groups present in the molecule (Shinde et al., 2020). Structural modifications, solvent effects, and substituent groups may lead to spectral shifts such as bathochromic (red) or hypsochromic (blue) shifts, as well as changes in absorption intensity known as hyperchromic and hypochromic effects (Sharma et al., 2002).

UV–Vis spectrophotometers are commonly classified as **single-beam** and **double-beam instruments**. Double-beam spectrophotometers offer enhanced accuracy and stability by simultaneously measuring sample and reference beams, thereby minimizing instrumental fluctuations (Xue et al., 2018).

In pharmaceutical analysis, UV–Vis spectroscopy is extensively employed for **drug identification, assay determination, dissolution testing, impurity profiling, and analytical method validation**. Method validation parameters such as specificity, accuracy, precision, linearity, detection limit, quantitation limit, range, and robustness ensure the reliability and reproducibility of analytical results (Meinrath & Lis, 2002; ICH, 2005). Owing to its non-destructive nature, minimal sample preparation, and wide applicability, UV–Vis spectroscopy remains a vital analytical technique in pharmaceutical quality control and research.

Principle of UV Spectroscopy

Ultraviolet–Visible (UV–Vis) spectroscopy is an analytical technique based on the interaction of ultraviolet and visible electromagnetic radiation with matter. It operates on the principle that molecules containing chromophores absorb radiation in the UV–Visible region (approximately 190–800 nm), resulting in the excitation of electrons from lower energy (ground state) orbitals to higher energy (excited state) orbitals. The amount of radiation absorbed at a particular wavelength is characteristic of the molecular structure and electronic configuration of the analyte (Skoog et al., 2017).

When monochromatic UV or visible light passes through a sample, part of the incident radiation is absorbed while the remainder is transmitted. The absorbed energy corresponds to specific **electronic transitions**, such as σ→σ*, n→σ*, π→π*, and n→π*, depending on the nature of chemical bonds, degree of conjugation, and presence of heteroatoms with non-bonding electrons (Shinde et al., 2020). Each compound exhibits a unique absorption spectrum, which can be used for qualitative identification.

The quantitative basis of UV spectroscopy is governed by the **Beer–Lambert law**, which states that the absorbance of a substance is directly proportional to the concentration of the absorbing species and the path length of the sample cell. Mathematically, it is expressed as:

$$A=\varepsilon c l A = \varepsilon c l$$

where A is absorbance, ε is the molar absorptivity ($L \cdot mol^{-1} \cdot cm^{-1}$), c is the concentration of the solution ($mol \cdot L^{-1}$), and l is the path length of the cell (cm). According to this law, a linear relationship exists between absorbance and concentration within a defined range, enabling the determination of unknown concentrations using calibration curves (Wittung et al., 1994).

The absorption of UV radiation is influenced by several factors, including solvent polarity, molecular structure, conjugation, and substituent effects. These factors may cause shifts in absorption maxima, such as **bathochromic (red) shifts** or **hypsochromic (blue) shifts**, as well as changes in absorbance intensity known as **hyperchromic** or **hypochromic effects** (Sharma et al., 2002). Such spectral variations provide valuable information regarding molecular environment and structural changes.

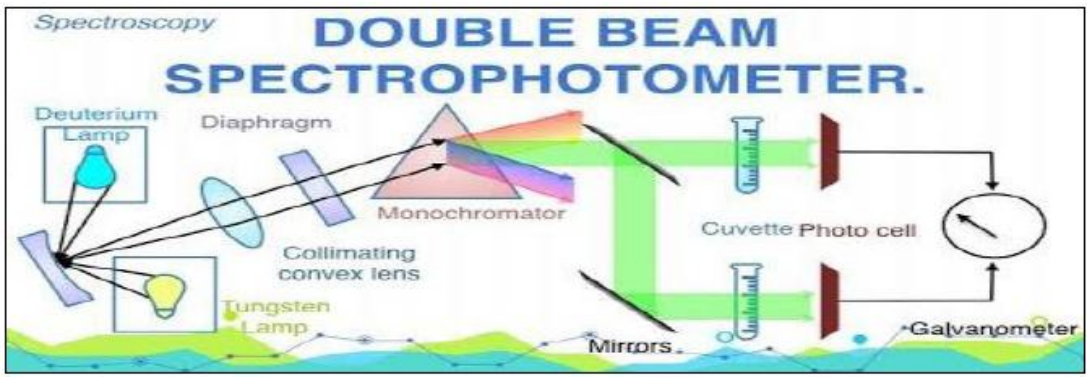

Figure 2: Double Beam Spectrophotometer.

In a UV–Vis spectrophotometer, radiation from a suitable light source is dispersed into monochromatic light using a monochromator and passed through the sample. The transmitted light is detected and converted into an electrical signal, which is processed to produce an absorption spectrum. The measurement of absorbance as a function of wavelength forms the basis for both qualitative and quantitative analysis (Patel et al., 2022).

Thus, UV spectroscopy is a simple, rapid, and reliable analytical technique that enables identification and quantification of substances based on their characteristic absorption of ultraviolet and visible radiation, making it an essential tool in pharmaceutical and analytical chemistry.

Drug Profile

1. Drug Name

Generic Name: Tetrabenazine

2. Chemical Information

- **Chemical Name:** (3-Isobutyl-9,10-dimethoxy-1,3,4,6,7,11b-hexahydro-2H-benzo[a]quinolizin-2-one)
- **Molecular Formula:** $C_{19}H_{27}NO_3$
- **Molecular Weight:** 317.42 g/mol
- **Chemical Class:** Benzoquinolizine derivative
- **Structure:** Tetrabenazine contains methoxy-substituted aromatic rings and conjugated systems, which contribute to its UV absorption properties.

3. Physical Description

- **Appearance:** White to off-white crystalline powder
- **Solubility:** Slightly soluble in water; soluble in organic solvents such as methanol and ethanol
- **Melting Point:** Approximately 163–166 °C
- **Stability:** Stable under normal storage conditions when protected from light and moisture

4. Pharmacological Category

- **Therapeutic Class:** Vesicular monoamine transporter 2 (VMAT2) inhibitor
- **Pharmacological Action:** Depletes monoamines such as dopamine, serotonin, norepinephrine, and histamine from nerve terminals

5. Mechanism of Action

Tetrabenazine selectively inhibits **vesicular monoamine transporter 2 (VMAT2)**, preventing the uptake of monoamines into synaptic vesicles. This results in reduced neurotransmitter release into the synaptic cleft, leading to decreased dopaminergic activity. The reduction in dopamine levels is responsible for its therapeutic effect in hyperkinetic movement disorders.

6. Therapeutic Uses

- Treatment of **chorea associated with Huntington's disease**
- Management of **hyperkinetic movement disorders**
- Occasionally used in **tardive dyskinesia** and other involuntary movement disorders under specialist supervision

7. Pharmacokinetics (Brief)

- **Absorption:** Well absorbed after oral administration
- **Metabolism:** Extensively metabolized in the liver to active metabolites (α-HTBZ and β-HTBZ)
- **Half-life:** Approximately 5–7 hours (metabolites may vary)
- **Excretion:** Primarily via urine

8. Dosage Forms and Strengths

- **Tablet Dosage Form:** Commonly available as 12.5 mg and 25 mg tablets
- **Route of Administration:** Oral

9. Adverse Effects (Common)

- Drowsiness and fatigue

- Depression and mood changes
- Parkinsonism-like symptoms
- Insomnia and anxiety
- Gastrointestinal disturbances

10. Contraindications

- Patients with untreated or inadequately treated depression
- Suicidal ideation
- Hypersensitivity to tetrabenazine
- Concomitant use with monoamine oxidase inhibitors (MAOIs)

11. Analytical Importance

Tetrabenazine possesses chromophoric groups that absorb in the ultraviolet region, making it suitable for analysis by **UV–Visible spectrophotometry**. UV spectroscopic methods are widely used for its **quantitative estimation in bulk drug and pharmaceutical dosage forms** due to simplicity, accuracy, and cost-effectiveness. Method validation as per ICH guidelines ensures reliability in routine quality control analysis.

12. Storage Conditions

- Store at **room temperature**
- Protect from **light and moisture**
- Keep in a well-closed container

The present study aimed to develop and validate a simple, accurate, and cost-effective UV spectrophotometric method for the assessment of percentage recovery of tetrabenazine in pharmaceutical dosage forms. Tetrabenazine, a VMAT2 inhibitor used in the treatment of chorea associated with Huntington's disease and other hyperkinetic disorders, requires precise dosage analysis due to its narrow therapeutic index. The method was optimized and validated in accordance with ICH guidelines, evaluating parameters such as wavelength selection, linearity, accuracy, precision, and recovery. The developed UV method offers a reliable, rapid, and economical approach suitable for routine quality control analysis of tetrabenazine tablets and has potential applicability in industrial quality assurance and related analytical studies.

1. Pre-formulation Studies

Tetrabenazine was subjected to pre-formulation evaluation to assess its basic physical and chemical properties, including organoleptic characteristics, melting point, solubility, pH, and drug–excipient compatibility, to ensure suitability for formulation and analytical development.

2. Organoleptic Evaluation

The drug was examined visually and by sensory perception for color, odor, and physical appearance to confirm identity and detect any signs of degradation or contamination.

3. Melting Point Determination

The melting point of Tetrabenazine was determined using a melting point apparatus by capillary method to assess purity and thermal stability.

4. Solubility Study

Solubility was evaluated qualitatively by visual observation in various solvents. Ethanol was selected based on superior solubility and clarity of solution.

5. pH Determination

The pH of the drug solution was measured using a calibrated digital pH meter to assess stability under different pH conditions.

6. FT-IR Analysis

FT-IR spectroscopy was performed using the KBr pellet method to identify characteristic functional groups and confirm drug identity.

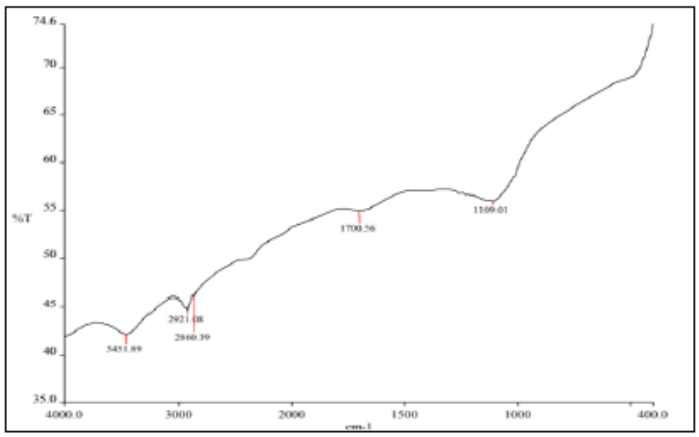

Figure 3: IR study of Tetrabenazine.

7. Determination of λmax

Standard solutions of Tetrabenazine were prepared in ethanol and scanned in the range of 200–400 nm using a UV-Visible spectrophotometer. The wavelength of maximum absorbance (λmax) was identified at **350 nm**.

8. Preparation of Standard Curve (Linearity Study)

Standard solutions in the concentration range of **20–120 µg/mL** were prepared and analyzed at 350 nm. A calibration curve of absorbance versus concentration was plotted to establish linearity.

9. Analysis of Tablet Dosage Form

Tablet powder equivalent to 10 mg of Tetrabenazine was dissolved in ethanol, sonicated, diluted appropriately, and analyzed by UV spectroscopy using ethanol as blank.

10. Method Validation (ICH Guidelines)

The developed UV method was validated for:

- Specificity
- Linearity
- Precision (intra-day, inter-day, repeatability)
- Accuracy
- Ruggedness
- Robustness
- Limit of Detection (LOD)
- Limit of Quantitation (LOQ)

11. Calculation of LOD and LOQ

LOD and LOQ were calculated using the standard deviation of response and slope of the calibration curve as per ICH recommendations.

Table 1: Result of Intraday Precision (three times on the same day)

Concentration (µg/mL)	Day 1 Absorbance (1) at 350.0nm	Day 1 Absorbance (2) at 350.0nm	Day 1 Absorbance (3) at 350.0nm
60	0.280	0.278	0.283
60	0.285	0.283	0.286
60	0.289	0.287	0.291
Mean	0.284667	0.282667	0.286667
SD	0.004509	0.004509	0.004041
%RSD	1.583	1.595	1.409
AVG % R.S.D	1.529		

Table 2: Optical Characteristics and Validation Study of Formulation.

Parameters	Tetrabenazine
Wavelength λ max nm	350.0 nm
Beer's law limit µg/ml	20-120
Correlation coefficient (R2)	0.9999
Slope	0.0041
Intercept	0.0351
SD	0.152932
% RSD	47.167
Precision	
Intraday (% RSD)	1.529
Interday (% RSD)	1.196
Repeatability (% RSD)	1.644
Ruggedness	
Analyst 1 (% RSD)	1.071
Analyst 2 (% RSD)	1.344
Robustness	
Temp.25^{0}C (% RSD)	1.088
Temp.30^{0}C (% RSD)	1.070
LOD (µg/ml)	125.4
LOQ (µg/ml)	380.0
% recovery	98.0%

RESULTS AND DISCUSSION

The pre-formulation studies of Tetrabenazine provided essential information regarding its physical and chemical characteristics, confirming the suitability of the drug for analytical method development. Organoleptic evaluation showed that Tetrabenazine is a white to off-white crystalline powder with a distinct odor, which is consistent with reported standards and indicates acceptable quality and identity. The melting point was observed at 137 °C, falling within the official reference range, thereby confirming the purity and thermal stability of the drug substance.

Solubility studies demonstrated that Tetrabenazine is sparingly soluble in water and DMSO but freely soluble in organic solvents such as ethanol and methanol. This limited aqueous solubility highlights the importance of selecting an appropriate organic solvent for analysis. The pH of the drug solution was found to be 4.3, indicating a mildly acidic nature, which supports chemical stability and compatibility with common pharmaceutical excipients.

UV-Visible spectrophotometric analysis revealed a maximum absorbance (λmax) at 350.0 nm, which was selected for further analytical measurements due to its high sensitivity and specificity. The calibration curve constructed over a concentration range of 20–120 µg/mL showed excellent linearity, with a correlation coefficient (R^2) of 0.9999, confirming adherence to Beer–Lambert's law. These results validate the suitability of the method for quantitative estimation.

FT-IR spectral analysis confirmed the presence of characteristic functional groups such as primary amine (N–H stretching), alkane (C–H stretching), carbonyl (C=O), and secondary alcohol (C–O stretching), which collectively verified the chemical structure and integrity of Tetrabenazine.

Method validation, performed in accordance with ICH guidelines, demonstrated satisfactory precision, repeatability, ruggedness, and robustness, with %RSD values consistently below 2%. The percentage recovery of 98.0% indicated good accuracy of the developed method. Although the reported LOD and LOQ values suggest moderate sensitivity, the overall validation results confirm that the UV spectrophotometric method is reliable, reproducible, and suitable for routine quality control analysis of Tetrabenazine in pharmaceutical dosage forms.

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