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UV Visible Spectroscopy : Analytical Technique for Measuring Paracetamol Drug Concentration and Evaluation its Stability Over Time

Prof. Tandale Sir, Nikam Ruturaj Balasheb, Khabale Vikas Shankar, Kemdharne Aishwarya Ashok, Khedkar Vaishnavi Parmeshwar
Aditya Diploma Institute of Pharmacy, Beed, Maharashtra, India

Abstract: *Paracetamol (acetaminophen) is a widely used analgesic and antipyretic drug. Monitoring its concentration and evaluating its stability are essential for ensuring therapeutic efficacy and safety. UV-visible (UV-Vis) spectroscopy has emerged as a convenient, cost-effective, and reliable analytical technique for this purpose. This review explores the principles of UV-Vis spectroscopy in relation to paracetamol analysis, recent advances in analytical protocols, and methodologies to assess the stability of paracetamol under various environmental and storage conditions.*

Pharmaceutical analysis plays a critical role in ensuring the safety, efficacy, and quality of drug substances and products. Among the various analytical techniques used in pharmaceutical quality control, UV-visible spectroscopy is one of the most widely employed due to its simplicity, accessibility, and cost-effectiveness. This review focuses on the use of UV-visible spectroscopy as a method for determining the concentration of paracetamol (acetaminophen) in pharmaceutical formulations, and for evaluating its stability under various environmental and storage conditions over time.

Paracetamol is a commonly used analgesic and antipyretic drug. Its widespread use across over-the-counter (OTC) medications and prescription formulations necessitates rigorous testing to ensure batch-to-batch consistency and to detect any degradation or loss of potency during its shelf life. Stability testing is equally important to determine the impact of environmental factors such as temperature, humidity, light, and pH on the chemical integrity of paracetamol.

Keywords: Paracetamol

I. INTRODUCTION

Paracetamol is one of the most commonly used over-the-counter drugs worldwide, favored for its effectiveness and minimal side effects when administered at therapeutic doses. However, improper storage or degradation over time can lead to the formation of toxic by-products such as p-aminophenol.

Therefore, accurate determination of its concentration and assessment of its stability are vital. UV-visible spectroscopy stands out among analytical tools due to its simplicity, non-destructive nature, and sensitivity. This technique is particularly effective for compounds like paracetamol, which absorb strongly in the UV range due to their aromatic structure.

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detect any degradation or loss of potency during its shelf life. Stability testing important to determine the impact of environmental factors such as temperature.

II. LITERATURE REVIEW

UV-Visible Spectroscopy in Pharmaceutical Analysis

1. Introduction to UV-Visible Spectroscopy in Pharmaceuticals:

UV-visible spectroscopy is a widely utilized analytical technique in pharmaceutical analysis due to its simplicity, cost-effectiveness, and non-destructive nature. It operates on the principle that molecules absorb ultraviolet or visible light at specific wavelengths, leading to electronic transitions. This absorption is proportional to the concentration of the analyte, following Beer-Lambert's law, making it suitable for quantitative analysis of drug substances.

2. Application in Drug Concentration Measurement:

Accurate determination of drug concentration is crucial for ensuring therapeutic efficacy and safety. UV-visible spectroscopy provides a rapid and reliable method for quantifying drug concentrations in various formulations. Studies have demonstrated its application in determining the concentration of active pharmaceutical ingredients (APIs) in tablets, syrups, and injectable solutions.

For instance, a study by Kumar et al. (2017) developed and validated a UV-spectrophotometric method for the estimation of a specific drug in tablet dosage forms. The method was found to be precise, accurate, and reproducible, adhering to ICH guidelines for analytical method validation.

3. Stability Studies Using UV-Visible Spectroscopy:

Stability studies are essential to assess the shelf-life and degradation pathways of pharmaceutical products. UV-visible spectroscopy plays a pivotal role in monitoring the stability of drugs under various stress conditions, including temperature, humidity, and light exposure.

Singh and Rehman (2015) reviewed the current trends in forced degradation studies, highlighting the importance of UV-visible spectroscopy in identifying degradation products and understanding degradation kinetics. Their review emphasized that UV spectroscopy, when coupled with chromatographic techniques, provides comprehensive insights into the stability profile of pharmaceutical compounds.

4. Method Validation and Regulatory Considerations:

For a UV-visible spectrophotometric method to be accepted for regulatory purposes, it must undergo rigorous validation. The International Council for Harmonisation (ICH) provides guidelines for method validation, covering parameters such as specificity, linearity, accuracy, precision, detection limit, quantitation limit, robustness, and system suitability.

A study by Kumar and Sharma (2017) discussed the development and validation of a UV-spectrophotometric method for drug estimation in pharmaceutical dosage forms. The method complied with ICH guidelines, demonstrating its suitability for routine quality control in pharmaceutical industries.

5. Limitations and Challenges:

Despite its advantages, UV-visible spectroscopy has certain limitations. Its sensitivity may be insufficient for detecting low-concentration drugs or degradation products in complex matrices. Additionally, interference from excipients and other components in pharmaceutical formulations can affect the accuracy of the results.

To overcome these challenges, researchers have explored the combination of UV-visible spectroscopy with other analytical techniques, such as high-performance liquid chromatography (HPLC) and mass spectrometry (MS), to enhance sensitivity and specificity.

III. AIM

To perform Analytical method of Paracetamol Tablets by using UV-spectrophotometric: ICH Q2 (R1) guidelines for validation of analytical procedures.

Indian Pharmacopoeia, 2010 vol. III, Govt. of India Ministry of health and Family Welfare Published by The Indian Pharmacopoeia Commission, Ghaziabad; 1861-1862.

REQUIREMETNS:Apparatus: 100ml & 10ml volumetric flasks, pipettes, beakers

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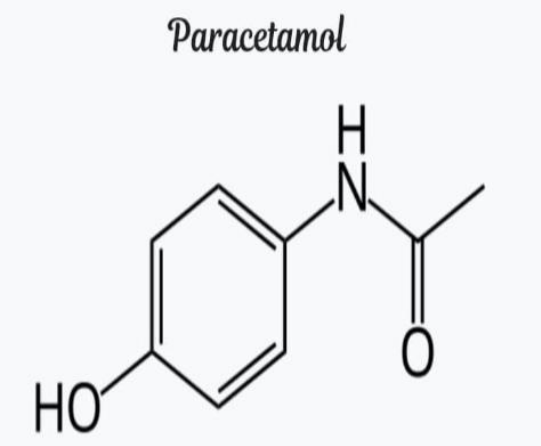
Reagents: Paracetamol API, Paracetamol Tablet, Methanol, Distilled Water.
Equipments:1 Shimadzu UV-1800 Sr. No.: A114550/08677
2) Shimadzu UV-1800 Sr. No.: A114549/08780
THEORY:General Description of Paracetamol:Name: Paracetamol INN or Acetaminophen USAN.Dose: 500 mg.
Chemical name: N-Acetyl-p-aminophenol.



OBJECTIVE:
1. Identification of Paracetamol: Paracetamol has a characteristic absorption peak (λmax) in the UV range, typically around 243 nm. UV-Vis spectroscopy helps confirm the presence of paracetamol by comparing the absorption spectrum with that of a reference standard.
2. Quantitative Analysis (Assay): To determine the concentration of paracetamol in tablets, syrups, or suspensions using Beer-Lambert's law:

$$A = E.C.L$$

3. Purity Check: Any shift in the absorption maximum or the presence of additional peaks may indicate impurities or degradation products in the formulation.
4. Stability Studie : UV-Vis spectroscopy is used to monitor the stability of paracetamol under various storage conditions by checking if the λmax or absorbance changes over time.
5. Detection of Degradation: Products Helps in identifying photodegradation or oxidation products, which may absorb at different wavelengths compared to intact paracetamol.
6. Validation of Analytical Methods: UV methods are validated for parameters such as linearity, accuracy, precision, specificity, and robustness as part of pharmaceutical quality control.

Principles of UV-Visible Spectroscopy in Drug Analysis:
UV-Visible spectroscopy relies on the absorption of ultraviolet or visible light by molecules. The absorbance is related to concentration by the Beer-Lambert law: A = epsilon·c·l, where A is absorbance, epsilon is molar absorptivity, c is concentration, and l is the path length. Paracetamol typically shows a maximum absorbance
(lambdamax) around 243-250 nm in aqueous and ethanol-based solutions.
UV-Visible spectroscopy is based on the absorption of ultraviolet or visible light by molecules, leading to electronic transitions. The absorbance (A) is governed by Beer-Lambert's Law:
A = \varepsilon c l absorbance is molar absorptivity is the concentration of the solution is the path length of the cuvette (typically 1 cm)Paracetamol exhibits strong absorbance in the UV range (usually around 243 nm), which makes it highly suitable for UV-Vis analysis.

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Methodology for Measuring Paracetamol Concentration:

Sample Preparation: Paracetamol samples are prepared in ethanol or distilled water, filtered, and analyzed immediately. Calibration Curve: A series of standard solutions with known concentrations is used to construct a calibration curve. Validation Parameters: Linearity, accuracy, precision, limit of detection (LOD), and limit of quantification (LOQ) are essential for validation.

To analyze paracetamol using UV-Vis spectroscopy, pharmaceutical samples (tablets, suspensions, syrups) are dissolved in an appropriate solvent (often water, methanol, or ethanol). The solution is then filtered and appropriately diluted.A calibration curve is constructed by measuring absorbance at the max

IV. PLAN OF WORK

"Quantitative Determination and Stability Analysis of Paracetamol Using UV-Visible Spectroscopy".

Objectives: To develop a UV-Visible spectrophotometric method for the quantification of paracetamol.To establish a calibration curve for paracetamol.To evaluate the stability of paracetamol under various storage conditions over time.

3. Materials and Reagents: Paracetamol standard ,Pharmaceutical formulation (tablets) Solvents: Distilled water, ethanol, or methanol, UV-transparent cuvettes, Glassware: Volumetric flasks, pipettes, beakers, etc. Analytical balance ,UV-Visible spectrophotometer.

4. Methodology:

4.1. Preparation of Standard Solutions Prepare a stock solution of paracetamol (e.g., 100 mg in 100 mL).Dilute to get working standards (e.g., 2, 4, 6, 8, 10, 12 µg/mL).

4.2. Wavelength Determination Scan standard solution (e.g., 10 µg/mL) in UV-V is range (200–400 nm).Identify λmax (maximum absorbance wavelength) — typically ~243 nm for paracetamol.

4.3. Calibration Curve Measure absorbance of the standard solutions at λmax.Plot Absorbance vs. Concentration to create a calibration curve.Determine linearity and regression equation.4.4. Sample Preparation Crush tablet or measure syrup dose.Dissolve in suitable solvent and dilute to fall within calibration range.Filter if necessary.

4.5. Drug Quantification : Measure absorbance of sample solution at λmax.Use calibration curve or equation to determine paracetamol concentration.

V. STABILITY STUDIES

5.1. Conditions for Stability Testing:

Store samples under:Room temperature, Elevated temperature (e.g., 40°C), Light exposurepH variation (acidic/basic conditions).

5.2. Time Points :Analyze at 0, 3, 7, 14, and 30 days (or other suitable intervals).

5.3. Evaluation :Measure changes in absorbance and calculate concentration. Compare results to initial concentration. Determine degradation rate, if any.

6. Data Analysis :Use linear regression for calibration curve. Calculate % degradation over time. Plot stability graphs: Concentration vs. Time.

7. Expected Outcome: Accurate, reproducible method for paracetamol quantification. max and linear concentration range identified. Data on paracetamol stability under different conditions.

Drug Profile: Paracetamol (Acetaminophen)

1. Generic Name :Paracetamol , Acetaminophen

2. Brand Names : Tylenol ,Panadol ,Calpol ,Crocin,Mapap, Feverallothers.

3. Drug Class : Analgesic (pain reliever) ,Antipyretic (fever reducer).

4. Mechanism of Action :Inhibits prostaglandin synthesis in the central nervous system by blocking the cyclooxygenase (COX) enzyme, primarily COX-2.Antipyretic effect via action on the hypothalamic heat-regulating center.Unlike NSAIDs, it has minimal anti-inflammatory activity due to weak peripheral COX inhibition .

5. Indications Mild to moderate pain (e.g., headache, muscle ache, backache, arthritis) Fever, Toothache, Cold and flu symptoms ,Osteoarthritis (symptomatic relief) .

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6. Dosage - Adults: 500 mg to 1000 mg every 4–6 hours as needed Maximum daily dose: 4000 mg (4 g)
Children: Dose based on weight (usually 10–15 mg/kg every 4–6 hours)
Maximum daily dose: 60 mg/kg/day (in some cases up to 90 mg/kg/day under medical supervision
7. Routes of Administration :Oral (tablets, capsules, syrup, suspension) Rectal (suppositories) Intravenous (IV solution, typically in hospital settings).
8. Onset and Duration :Onset: 30 minutes (oral); 5–10 minutes (IV) Duration: 4–6 hours
9. Side Effects :Common (generally rare at therapeutic doses) ,Nausea, Rash ,Headache .
Serious (especially in overdose): Hepatotoxicity (liver damage) ,Renal impairment (in high doses) ,Allergic reactions (rare)
10. Contraindications Known hypersensitivity to paracetamol Severe hepatic impairment or active liver disease.
11. Precautions :Use cautiously in patients with liver disease or chronic alcohol use Avoid combining with other medications containing paracetamol to prevent overdose.
12. Drug Interactions - Alcohol: Increases risk of liver toxicity
Warfarin: May increase bleeding risk with long-term use
Enzyme inducers (e.g., rifampin, carbamazepine): May increase metabolism and reduce efficacy
13. Pregnancy and Lactation Pregnancy Category B (FDA): Generally considered safe Lactation: Safe – excreted in small amounts in breast milk.
14. Overdose Symptoms: Nausea, vomiting, sweating, fatigue (early signs) ,Liver failure (after 24–72 hours) ,Encephalopathy, coagulopathy (severe cases)
Antidote: N-acetylcysteine (NAC) – most effective within 8–10 hours of overdose
15. Storage :Store at room temperature, away from moisture and heat.
Stability Studies of Paracetamol:
Environmental Inflnces: Paracetamol is sensitive to light, heat, and humidity. Forced Degradation Studies: Stability is assessed under stress conditions including thermal, photolytic, hydrolytic, and oxidative degradation. Changes in UV-Vis spectra are used to monitor degradationParacetamol is susceptible to degradation when exposed to high temperature, humidity, light, and oxidative conditions. Degradation products may include p-aminophenol and other toxic intermediates, which necessitate stability monitoring.
Applications and Advantages0
Quality Control, Shelf-life Estimation, and Formulation Studies are common applications. Advantages include non-destructive analysis, cost-effectiveness, and rapid results suitable for routine analysis.
Limitations and Complementary Techniques
While UV-Vis is effective for preliminary analysis, it lacks specificity. Complementary techniques like HPLC or mass spectrometry may be needed for detailed analysis.

VI. CONCLUSION

UV-visible spectroscopy is a vital tool in pharmaceutical analysis, offering a straightforward approach to quantify paracetamol and evaluate its stability over time. Its integration into drug development and quality assurance processes ensures safety and effectiveness of pharmaceutical products. UV-visible spectroscopy remains a cornerstone in pharmaceutical analysis for measuring drug concentration and evaluating stability over time. Its simplicity, cost-effectiveness, and non-destructive nature make it an invaluable tool in both research and quality control settings. Ongoing advancements in instrumentation and data analysis techniques are expected to further enhance its applicability and reliability in pharmaceutical sciences.

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