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# Comparative Evaluation of Marketed Tablet Formulations by Uv Spectroscopy

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**ABSTRACT:**
This study explores the application of UV-Visible spectrophotometry for the quantitative analysis and quality assessment of pharmaceutical drugs, specifically Paracetamol, Ofloxacin, Aspirin, Amlodipine. UV-Visible spectrophotometry is a widely used analytical technique that measures the absorption of ultraviolet or visible light by chemical substances, based on the principles of the Beer-Lambert law. This method enables the determination of drug concentration and purity by evaluating the relationship between absorbance and concentration at specific wavelengths. In this research, standard and sample solutions of drugs were prepared using appropriate solvents, and their absorbance was measured at their respective maximum wavelengths (λmax). Calibration curves were constructed by plotting absorbance against known concentrations of the standard solutions, establishing linear equations for each drug. These calibration models were then used to estimate the concentration of active pharmaceutical ingredients in commercial tablet formulations. The study also reviewed the pharmaceutical profiles, pharmacokinetics, mechanisms of action, and manufacturing details of both drugs to provide a comprehensive understanding of their analytical and therapeutic significance. The aim of this work is to highlight the reliability, simplicity, and cost-effectiveness of UV spectrophotometry as a tool for routine quality control in pharmaceutical analysis, especially in ensuring compliance with pharmacopeial standards.

**KEYWORDS**: Calibration Curve, UV Spectroscopy, Paracetamol, Ofloxacin, Aspirin Amlodipine, % Purity

**AIM AND OBJECTIVES:**

**Aim:** To evaluate the percentage purity of commercially available Paracetamol, Aspirin, Ofloxacin and Amlodipine tablet formulations using UV-Visible spectrophotometry based on the principles of Beer-Lambert law.

**Objectives of the Research:**

- To study the principles and instrumentation of UV-Visible spectrophotometry.
- To prepare and analyse standard and sample solutions of each drug.
- To determine the maximum absorption wavelength (λmax) for each drug.
- To construct calibration curves by plotting absorbance vs. concentration.
- To apply Beer-Lambert's law to calculate the concentration of drug samples.
- To assess the percentage purity of commercial drug formulations.
- To compare the results with pharmacopeial standards (IP and USP) for quality evaluation.
- To demonstrate the efficacy of UV spectrophotometry in pharmaceutical quality control.

**Need for the Research:**

- To ensure the quality, safety, and efficacy of commonly used pharmaceutical drugs like Paracetamol and Amlodipine.
- To identify substandard or degraded formulations in the market that may pose health risks.
- To support regulatory compliance with Indian Pharmacopoeia (IP) and United States Pharmacopeia (USP) standards.
- To improve quality control practices in pharmaceutical manufacturing and testing laboratories.

## I. INTRODUCTION [1]

**Definition**

- UV Spectroscopy measures absorption of UV light (200–400 nm) by molecules, helping determine their concentration and structure.

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**Principle**

- Based on electronic transitions: molecules absorb UV light and shift from ground to excited states, producing a characteristic absorbance.

**Beer-Lambert Law**

- Formula: $A=\varepsilon \cdot c \cdot l$

Where:

- A: Absorbance
- ε: Molar absorptivity
- c: Concentration
- l: Path length (usually 1 cm)

**Assumptions:**

1. Homogeneous solution
2. Monochromatic light
3. Independent absorbers
4. Constant path length and concentration
5. No scattering or fluorescence

**Instrumentation Components** [2]

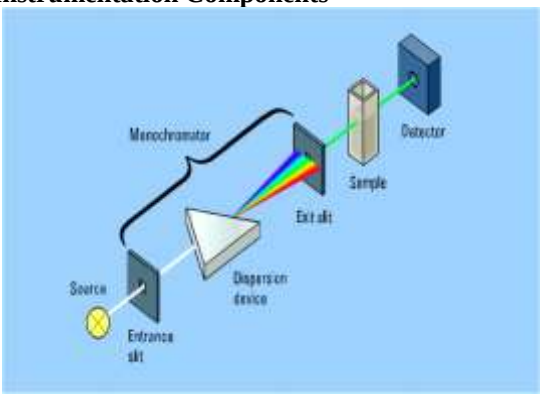


**Figure no 1: Instrumentation of UV Spectrophotometer**

1. **Light Source**:

- Deuterium lamp for UV (190–400 nm)
- Tungsten lamp for visible (400–800 nm)

2. **Monochromator:**

- Isolates specific wavelengths using slits and gratings

3. **Sample Holder**:

- Quartz cuvettes for UV, glass/plastic for visible

4. **Sample:**

- Usually in solution; absorbs light based on structure

5. **Detector:**

- Photodiode or PMT converts light into electrical signals

6. **Signal Processor:**

- Converts signals into spectra (absorbance vs. wavelength)

7. **Exit Slit:**

- Controls light resolution before it reaches the sample

8. **Spectral Range:**

- UV: 200–400 nm
- Visible: 400–800 nm

9. **Software Functions:**

- Wavelength control, baseline correction, spectrum analysis, concentration calculation

❖ **Applications of UV spectroscopy:**[3]

UV spectroscopy has a wide range of applications across many fields, especially in chemistry, biology, environmental science, and material science. Below are some of the key applications of UV spectroscopy in detail:

1. Quantitative Analysis (Concentration Determination)
2. Identification and Characterization of Compounds
3. Kinetic Studies
4. Structural Elucidation
5. Protein and Nucleic Acid Analysis
6. Environmental Monitoring
7. Forensic Analysis
8. Photochemistry Studies

**Advantages of UV spectroscopy:** [4]

1. Non-destructive Technique
2. Simplicity and Ease of Use
3. High Sensitivity and Detection Limits
4. Rapid and Real-Time Analysis
5. Wide Range of Applications
6. Quantitative Analysis Using Beer's Law
7. Minimal Sample Preparation
8. Ability to Analyse Various Forms (Solid, Liquid, or Gas)

❖ **Limitations of UV spectroscopy:** [5]

1. Limited Sample Types
2. Interference from Solvents
3. Poor Sensitivity for Low Absorbing Compounds
4. Beer's Law Limitations (Linear Range)

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**Introduction To Method:**[6]

The **Calibration Curve Method** is a technique to find the concentration of an unknown sample by comparing its measured response to a curve plotted from standards of known concentration.

**Steps for Calibration Curve Method:**

**Prepare Standard Solutions:**

Make several solutions with known concentrations of the analyte.

**Measure Responses:**

Measure the instrument response (e.g., absorbance, peak area) for each standard.

**Plot Calibration Curve:**

Plot the instrument response (y-axis) vs. concentration (x-axis).

**Fit the Curve:**

Fit a straight line (or appropriate curve) through the points; most commonly a linear regression line.

**Measure Unknown Sample:**

Measure the response of the unknown sample under the same conditions.

**Determine Concentration:**

Use the calibration curve equation to calculate the concentration of the unknown by substituting the sample's response.

**Formula:** If the calibration curve is linear, the relationship is usually:

$y = mx + c$

Where: y = instrument response (e.g., absorbance)

x = concentration of analyte

m = slope of the calibration curve

c = y-intercept

**Instrumentation model:**

| Feature | Details |
|---|---|
| **Instrument Name** | UV-VIS SPECTROPHOTOMETER |
| **Manufacturer** | Shimadzu Corporation |
| **Type** | UV-1900 Series |
| **Model** | UV 1900 1 (A12535981410) |
| **UV Range** | 190 nm – 1100 nm (varies slightly by model) |
| **Detectors** | Photomultiplier tube (PMT), Silicon photodiode |
| **Light Source** | Deuterium lamp (UV) and Tungsten lamp (visible) |
| **Software** | LabSolutions UV-Vis |
| **Version** | 1.12 |

**Table No. 1: Shimadzu 1900 Series Details**

## EXPERIMENTAL WORK

## A. PARACETAMOL

### 1. DRUG PROFILE [7]

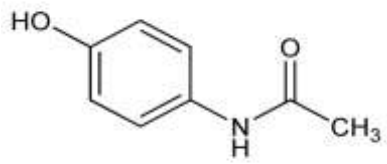


**Figure No 2: Structure Of Paracetamol**

- Generic Name: Paracetamol
- Also Known As: Acetaminophen
- Chemical Name: N-(4-hydroxyphenyl) acetamide
- Molecular Formula: $C_8H_9NO_2$
- Molecular Weight: 151.16 g/mol
- Drug Class: Analgesic and Antipyretic
- Mechanism of Action: Inhibits prostaglandin synthesis in the central nervous system, primarily acting on the hypothalamic heat-regulating centre.
- Uses: Relief of mild to moderate pain (e.g., headache, muscle pain, dental pain) and fever reduction.
- Dosage (Adults): 500–1000 mg every 4–6 hours; maximum 4000 mg/day
- Absorption: Rapid from gastrointestinal tract
- Half-life: 2–3 hours
- Metabolism: Primarily in the liver (glucuronidation and sulfation)
- Excretion: Renal
- Common Side Effects: Rash, nausea; hepatotoxicity in overdose
- Advantages: Safe for most populations, minimal gastric irritation.

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## 2. SAMPLE COLLECTION:

**1.Dolo 650 Mg**


**Figure No 3: Dolo 650 mg**

| | |
|---|---|
| **Manufactured By** | Micro Labs Limited |
| **Mfg. lic. No.:** | M/600/2012 |
| **Batch No.:** | DOB534237 |
| **Mfg. Date:** | JAN 2023 |
| **Exp. Date:** | DEC 2025 |
| **Strength** | 650 mg |
| **M.R.P.** | 33.76rs for 15 Tablets |

**Table No 2: Dolo 650 mg Details**

**2. Paracip-500 Mg**


**Figure No 4: Paracip-500 Mg**

| | |
|---|---|
| **Manufactured by:** | CIPLA LTD |
| **Mfg. Lic. No.:** | 43/UA/2010 |
| **Batch No.:** | CH40454 |
| **Mfg. Date:** | NOV 2024 |
| **Exp. Date:** | OCT 2027 |
| **Strength** | 500 mg |
| **M.R.P.** | 10.08(10 tablets) |

**Table No 3: Paracip-500 Mg Details**

## 3. MATERIAL AND METHODS:[8]

**Materials**

- Paracetamol (standard, pure API)
- Commercial Paracetamol tablets (label claim: 500 mg,650mg)
- 0.1 N Sodium Hydroxide (NaOH) solution
- Distilled water
- Analytical balance
- Volumetric flasks (10 mL, 100 mL,50ml)
- Pipettes, filter paper
- UV-Visible Spectrophotometer (Range: 257 nm)

**Method**

**Preparation of Standard Stock Solution**

- **Dissolve 50 mg** of pure **Paracetamol** in 50 ml of 0.1 N NaOH.

**Preparation of Working Standard Solution**

1. Pipette **5 mL** of the standard stock solution into **50 ml 0.1 N NaOH**.
2. Further dilutions (e.g., 0.5,1,1.5,2,2.5 ml in 10 ml solvent) may be prepared to construct a calibration curve by suitable dilution with 0.1 N NaOH.

**Preparation of Sample Solution**

1. Weigh **20 tablets** of paracetamol, calculate the average weight.
2. Powder the tablets finely in a mortar.
3. Weigh accurately a portion equivalent to **50 mg of Paracetamol**.
4. Transfer the weighed powder into a **50 mL volumetric flask**.
5. Add about **25 mL of 0.1 N NaOH** and sonicate for **10–15 minutes** to dissolve.

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6. Filter the solution through Whatman No. 41 filter paper.
7. Wash the residue with 0.1 N NaOH, combine the filtrates, and make up the volume to 50 mL with 0.1 N NaOH.
8. Pipette **5 mL** of this solution into another 100 mL volumetric flask and dilute to the mark with 0.1 N NaOH. Final concentration.
9. Further dilutions can be made to match the standard concentration used for analysis. (2 µg/mL)

**UV-Vis Spectrophotometric Analysis**

1. Scan the standard solution in the range of **200–400 nm** to determine λmax (typically around **257 nm** for paracetamol in NaOH)
2. Measure the absorbance of the sample and standard solutions at λmax.
3. Plot the calibration curve of absorbance vs. concentration for the standard
4. Determine the concentration of Paracetamol in the tablet sample using the calibration curve.

## 4. RESULTS OF ANALYSIS:

### 1.Standard paracetamol

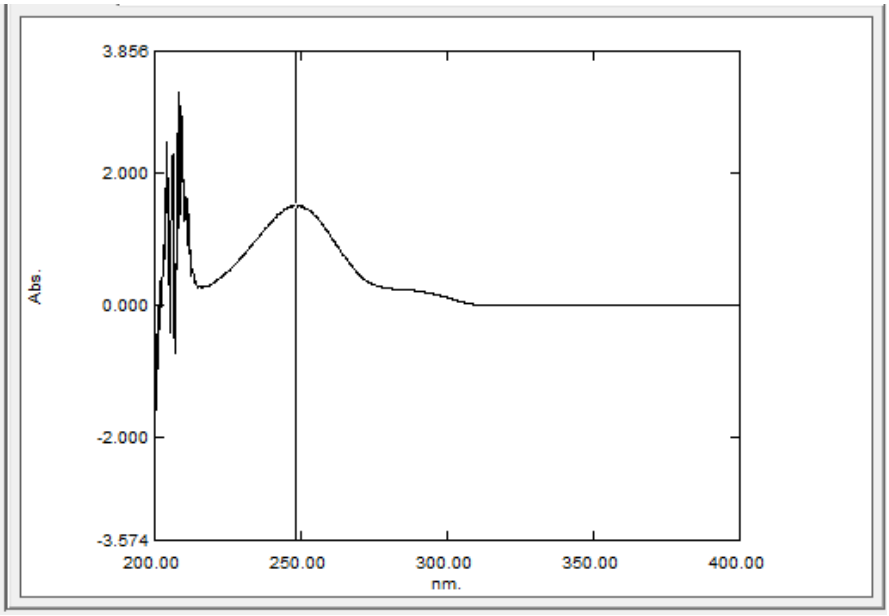
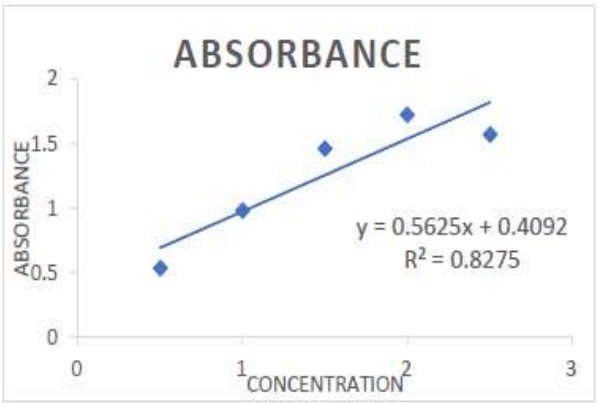



**Fig No 5: λmax Paracetamol Standard (257nm)**

| Concentration (ug/ml) | Absorbance |
|---|---|
| 0.5 | 0.5329 |
| 1 | 0.9799 |
| 1.5 | 1.4621 |
| 2 | 1.7218 |
| 2.5 | 1.5683 |

**Table No 4: Concentration Vs Absorbance**




**Graph No 1: Calibration Curve of Standard**

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**2. Sample Paracetamol:**

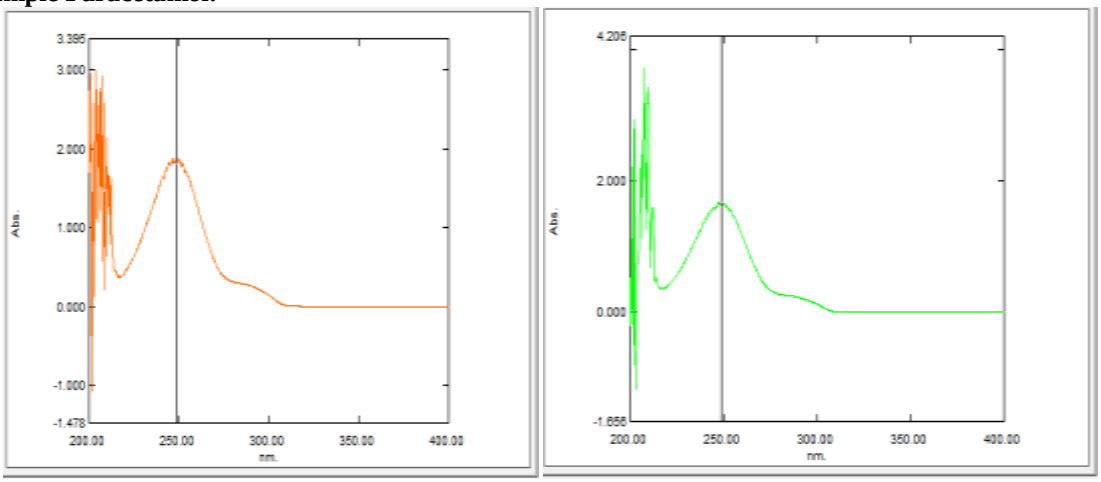


**Figure No 6: λmax of Dolo 650mg And Paracip 500 mg at 257 Nm**

**5. CALCULATIONS:**

**Formula Used:**[10]

The calculations are based on the linear equation of the calibration curve:

**y = mx + c**, where:

- **y** is the absorbance of the sample
- **m** is the slope of the calibration curve (from standard data)
- **c** is the intercept
- **x** is the concentration of the sample (solved from the equation)
- Then, **% Purity = (Calculated Concentration / Label Claim) × 100**

**Paracetamol**

**Sample 1 (650 mg):** y = 1.450, m = 0.5625, c = 0.4092

→ x = (1.480 - 0.4092) / 0.5625 = 1.90

→ **% Purity** = (1.90 / 2) × 100 = **95%**

**Sample 2 (500 mg):** y = 1.550, m = 0.5625, c = 0.4092

→ x = (1.550 - 0.4092) / 0.5625 = 2.02

→ **% Purity** = (2.02 / 2) × 100 = **101%**

**B. OFLOXACIN**

**1.DRUG PROFILE** [9]

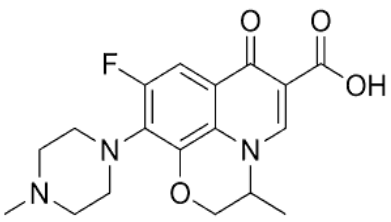


**Figure no.7: Structure of Ofloxacin**

- Generic Name: Ofloxacin
- Brand Name: Oflox, Floxin
- Chemical Name: (±)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid
- Molecular Formula: $C_{18}H_{20}FN_3O_4$
- Molecular Weight: 361.37 g/mol
- Drug Class: Fluoroquinolone Antibiotic
- Mechanism of Action: Inhibits bacterial DNA gyrase and topoisomerase IV, essential for DNA replication, repair, and transcription.
- Uses: Treatment of urinary tract infections, respiratory tract infections, skin infections, prostatitis, gonorrhoea, and bacterial conjunctivitis.
- Dosage (Adults): 200–400 mg every 12 hours depending on infection; dose adjusted in renal impairment
- Absorption: Rapid and nearly complete oral absorption (bioavailability ~98%)
- Half-life: 4–7 hours
- Metabolism: Limited hepatic metabolism
- Excretion: Primarily renal, mostly unchanged in urine
- Common Side Effects: Nausea, diarrhoea, headache, dizziness; risk of tendon rupture, QT prolongation
- Advantages: Broad-spectrum, high tissue penetration, effective oral and IV options

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## 2.SAMPLE COLLECTION

### 1. Oflox 400 Mg


Figure no 8: Oflox 400 mg

| | |
|---|---|
| Manufactured by: | Golden Cross Pharma Ltd |
| Mfg. Lic. No.: | M/481/08 |
| Batch No.: | ASQ032X |
| Mfg. Date: | MAY 24 |
| Exp. Date: | APR 27 |
| strength | 400 mg |
| M.R.P. | 353.57rs (10 tablets) |

Table no 5: Oflox 400 mg details

### 2. Oflox 200 Mg

Figure No 9: Oflox 200 Mg

| | |
|---|---|
| Manufactured by: | CIPLA Ltd. |
| Mfg. Lic. No.: | M/435/08 |
| Batch No.: | 45B01688 |
| Mfg. Date: | NOV 23 |
| Exp. Date: | JAN 26 |
| strength | 200 mg |
| M.R.P. | 87.42rs(10 tablets) |

Table No 6 : Oflox 200 Mg Details

## 3. MATERIALS AND METHODS [10]

### Materials

- Ofloxacin pure drug (standard) – obtained from a certified supplier.
- Marketed Ofloxacin tablets – labelled to contain 200 mg or 400 mg of Ofloxacin.
- Distilled water – used as the solvent throughout the analysis.
- Volumetric flasks – 10 mL, 50 mL, and 100 mL capacity.
- UV-Visible Spectrophotometer – with 1 cm quartz cuvettes.
- Digital balance – with precision ±0.1 mg.
- Filter paper – Whatman No. 41.

### Preparation of Standard Solution

1. Accurately weigh 50 mg of Ofloxacin reference standard using a digital balance.
2. Transfer the weighed quantity into a 50 mL volumetric flask.
3. Add about 35 mL of distilled water and sonicate (if needed) to dissolve the drug completely.
4. Make up the volume to 50 mL with distilled water. This gives a stock solution of 500 µg/ml.
5. Pipette out 5 mL of this stock solution into another 50 mL volumetric flask and dilute to the mark with distilled water to get a working standard of 50 µg/ml.
6. Further dilutions may be prepared (e.g., 0.5,1,1.5,2,2,5 µg/mL) for linearity and

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calibration by appropriately diluting with water.

**Preparation of Sample Solution (Tablet Formulation)**

1. Weigh and finely powder 20 tablets.
2. Accurately weigh a quantity of tablet powder equivalent to 50 mg of Ofloxacin.
3. Transfer the powder into a 50 mL volumetric flask and add about 35 mL of distilled water.
4. Sonicate for 10 minutes to ensure complete extraction of the drug.
5. Cool and make up the volume to 50 mL with distilled water.
6. Filter the solution through Whatman filter paper No. 41.
7. Pipette 5 mL of the filtrate into another 50 mL volumetric flask and dilute to volume with distilled water. This yields a test solution of 50 µg/ml.
8. Further dilutions may be made from this stock as required for UV analysis. (2 µg/mL)

**UV Analysis Procedure**

1. Measure the absorbance of both standard and sample solutions at the λmax of Ofloxacin (typically around 287 nm).
2. Use distilled water as a blank.
3. Prepare a calibration curve using standard dilutions (0.5-2.5µg/mL) and determine the concentration of the sample from the curve.

## 4.RESULTS OF ANALYSIS

### 1. Standard Ofloxacin

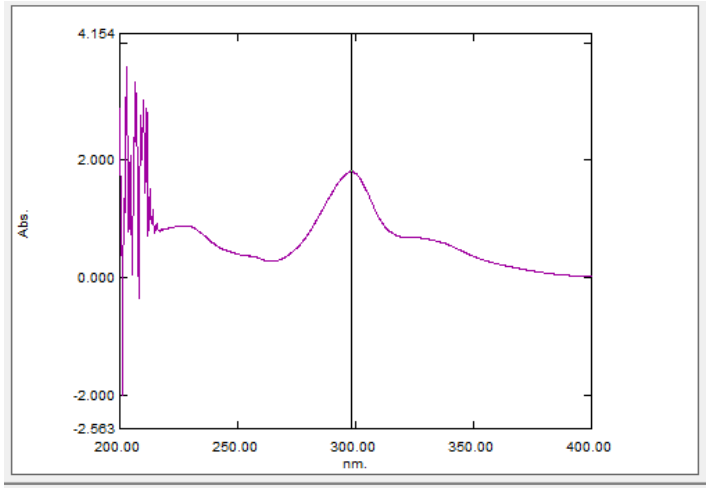
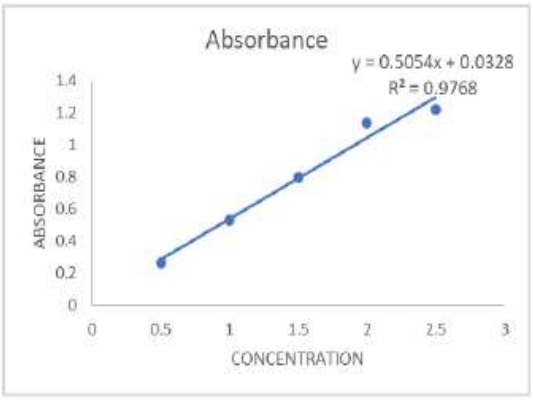



**Figure No. 10: λmax of Ofloxacin Standard (287nm)**

| Concentration | Absorbance |
|---|---|
| 0.5 | 0.2636 |
| 1 | 0.5314 |
| 1.5 | 0.7968 |
| 2 | 1.1397 |
| 2.5 | 1.2229 |

**Table no 7: concentration vs absorbance**




**Graph No 2: Calibration Curve of Standard**

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**2. Sample Ofloxacin**

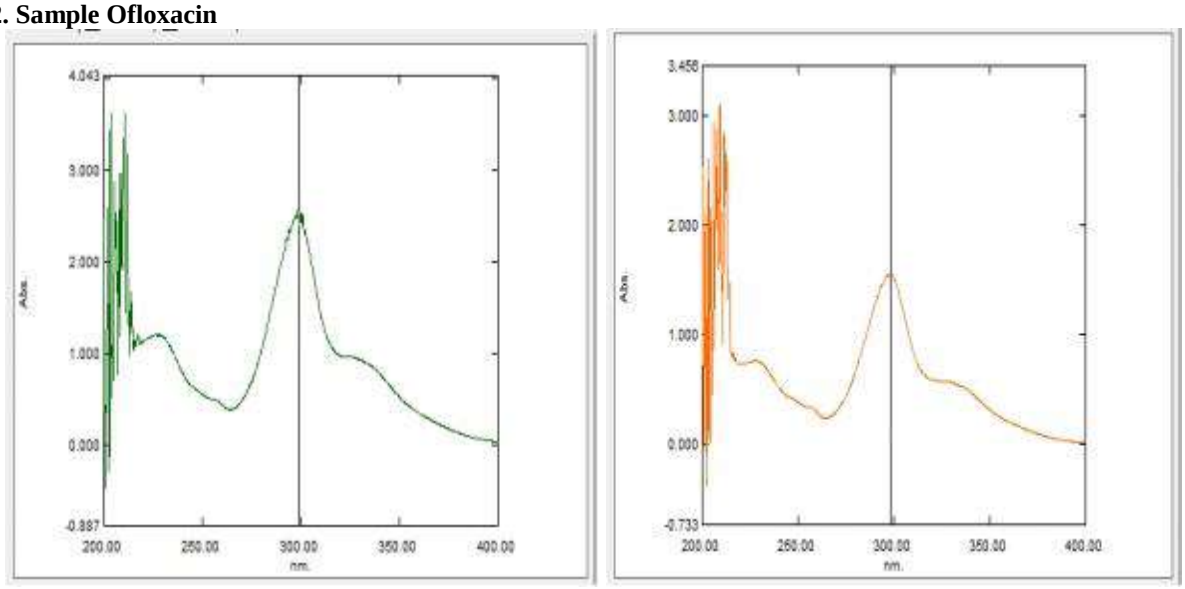


**Figure no 11: λmax of oflox 400 mg and oflox 200 mg sample**

**5.CALCULATIONS**

**Sample 1(400 mg):** y = 1.002, m = 0.5054, c = 0.0328

→ x = (1.002-0.0328) / 0.5054 = 1.9

→ % Purity = (1.9/ 2) × 100 = 95%

**Sample 2 (200 mg):** y = 1.0995, m = 0.5054, c = 0.0328

→ x = (1.0995 - 0.0328) / 0.5054 = 2.11

→ % Purity = (2.11 / 2) × 100 = 105.5%

**C. ASPIRIN**

**1. DRUG PROFILE [11]**

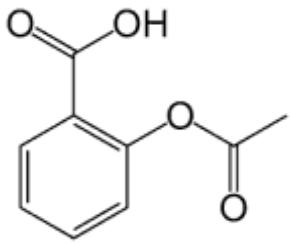


**Figure No.12: Structure of Aspirin**

- Generic Name: Aspirin
- Also Known As: Acetylsalicylic acid (ASA)
- Chemical Name: 2-Acetoxybenzoic acid
- Molecular Formula: $C_9H_8O_4$
- Molecular Weight: 180.16 g/mol
- Drug Class: NSAID (Nonsteroidal Anti-Inflammatory Drug), Antiplatelet
- Mechanism of Action: Irreversibly inhibits cyclooxygenase (COX-1 and COX-2), reducing prostaglandin and thromboxane A2 synthesis
- Uses: Pain relief, fever reduction, anti-inflammatory in arthritis; prevention of heart attack, stroke, and clot formation
- Dosage (Adults):
- For pain/fever: 325–650 mg every 4–6 hours (max 4 g/day)
- For antiplatelet use: 75–325 mg once daily
- Absorption: Rapid from stomach and upper intestine
- Half-life:
- 2–3 hours (low dose)
- Up to 15 hours (high dose, due to saturation metabolism)
- Metabolism: Liver (to salicylic acid)
- Excretion: Renal (pH-dependent excretion)
- Common Side Effects: Gastric irritation, bleeding, nausea, tinnitus (in overdose), Reye's syndrome (in children)
- Advantages: Effective antiplatelet agent; inexpensive and widely available

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## 2. SAMPLE COLLECTION

**1.Ecosprin 150 mg**


**Figure no 13: Ecosprin 150 mg**

| | |
|---|---|
| **Manufactured by:** | USV Private Limited |
| **Mfg. Lic. No.:** | D/354/07 |
| **Batch No.:** | 73R48201 |
| **Mfg. Date:** | MAR 24 |
| **Exp. Date:** | JUN 26 |
| **Strength** | 150 mg |
| **M.R.P.** | 35.57RS (14 tablets) |

**Table no 8: Ecosprin 150 mg details**

**2.Ecosprin 75 mg**


**Figure No 14: Ecosprin 75 Mg**

| | |
|---|---|
| **Manufactured by:** | USV Private Limited |
| **Mfg. Lic. No.:** | E/243/09 |
| **Batch No.:** | 47P02386 |
| **Mfg. Date:** | JAN 23 |
| **Exp. Date:** | DEC 25 |
| **Strength** | 75 mg |
| **M.R.P.** | 24.57rs (14 tablets) |

**Table No 9: Ecosprin 75 Mg**

## 3. MATERIAL AND METHODS [12]

**Materials**

- Aspirin tablets (marketed formulation containing 75 mg and 150mg Aspirin per tablet)
- Aspirin standard (analytical grade, ≥99% purity)
- Ethanol (95%) (analytical reagent grade)
- Distilled water
- UV-Visible spectrophotometer with 1 cm quartz cuvettes
- Analytical balance (sensitivity ±0.1 mg)
- Volumetric flasks (10 mL, 50 mL, 100 mL)
- Pipettes and micropipettes

**Preparation of Standard Solution**

1. Accurately weigh 50 mg of Aspirin standard using an analytical balance.
2. Transfer the weighed standard into a 50 ml volumetric flask.
3. Add about 35 ml of 95% ethanol and sonicate if necessary to dissolve.
4. Make up the volume to 50 ml with 95% ethanol to obtain a stock solution of 500 µg/ml.
5. From this stock, pipette 5 ml into another 50 ml volumetric flask and dilute to the mark with ethanol to prepare a 50 µg/ml working standard.
6. Prepare further dilutions (e.g.,0.5,1,1.5,2,2.5 ml in 10 ml) as needed for calibration by pipetting appropriate aliquots into 10 ml volumetric flasks and diluting with ethanol.

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**Preparation of Sample Solution**

1. Accurately weigh and finely powder 20 Aspirin tablets.
2. Weigh a quantity of the powder equivalent to 50 mg of Aspirin and transfer to a 100 mL volumetric flask.
3. Add about 35 ml of 95% ethanol, sonicate for 10 minutes to ensure complete extraction.
4. Filter through Whatman No.1 filter paper.
5. Wash the residue with small portions of ethanol and combine filtrates.
6. Make up the volume to 100 ml with ethanol (resulting in a 500 µg/ml stock solution).
7. Further dilute an appropriate volume (e.g., 0.5,1,1.5,2,2.5ml) to obtain a 50 µg/ml sample solution for UV analysis.

**UV Analysis**

1. Determine the maximum absorbance (λmax) of standard Aspirin using a UV-Vis spectrophotometer, scanning from 200–400 nm. The typical λmax for Aspirin is around 275 nm.
2. Measure the absorbance of standard and sample solutions at λmax using quartz cuvettes (1 cm path length).
3. Prepare a calibration curve from standard solutions and determine the concentration of Aspirin in the sample solution using the regression equation.

## 4. RESULTS OF ANALYSIS

### 1. Standard Aspirin

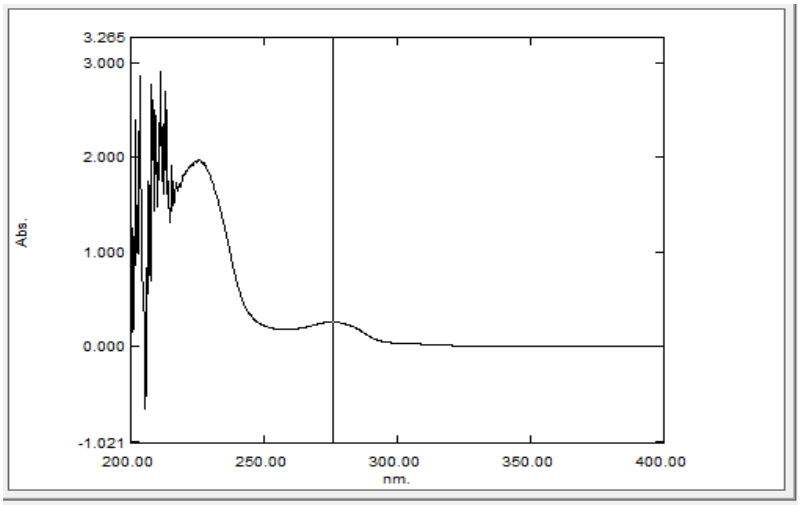
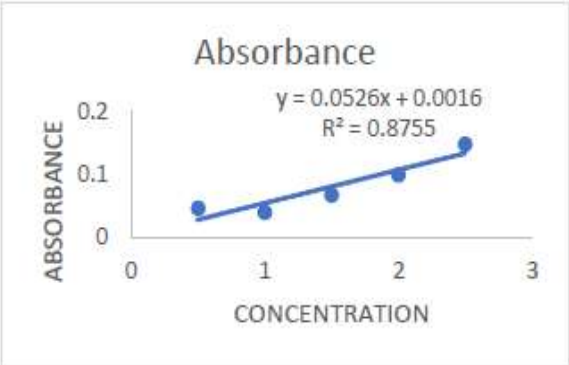



**Figure no 15: λmax of aspirin standard (276nm)**

| Concentration | Absorbance |
|---|---|
| 0.5 | 0.0465 |
| 1 | 0.0401 |
| 1.5 | 0.0677 |
| 2 | 0.0998 |
| 2.5 | 0.1481 |

**Table no 10: concentration vs absorbance**




**Graph No 3: Calibration Curve of Standard Sample Aspirin**

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**2. Sample aspirin**

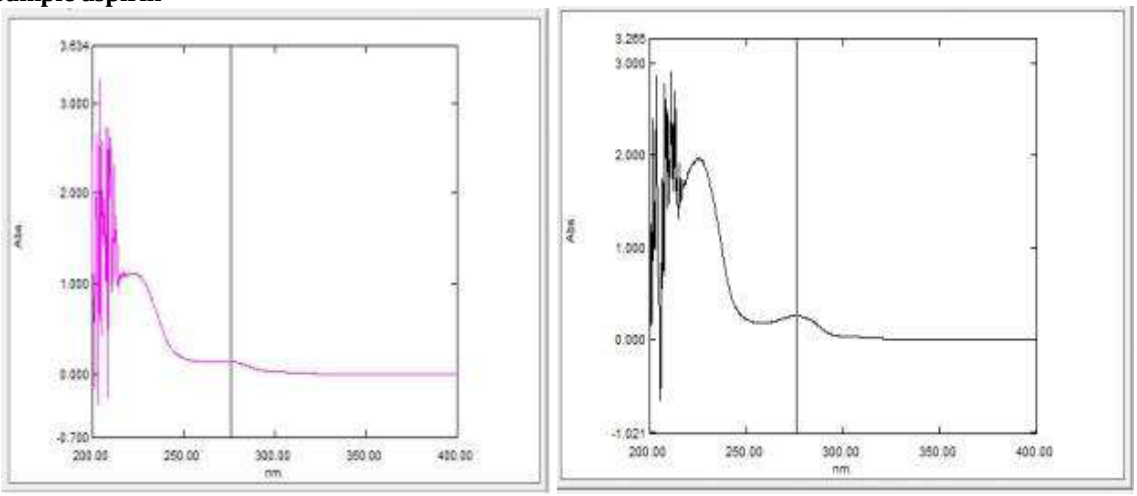


**Figure no 16: λmax of Ecosprin 150 mg and Ecosprin 75 mg at 276nm**

**5.CALCULATIONS**

**Sample 1(150 mg):** y = 0.1005, m = 0.0526, c = 0.0016

→ x = (0.1005-0.0016) / 0.0526 = 1.88

→ % Purity = (1.88/ 2) × 100 = 94%

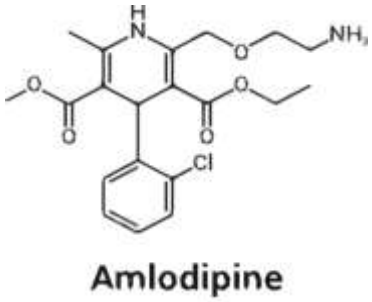
**Sample 2 (75 mg):** y =0.1011, m = 0.0526, c = 0.0016

→ x = (0.1011 - 0.0016) / 0.0526 = 1.89

→ % Purity = (1.89 / 2) × 100 = 94.5%

**D. AMLODIPINE**

**1. DRUG PROFILE** [13]




Amlodipine

**Figure No 17: Structure Of Amlodipine**

- Generic Name: Amlodipine
- Drug Class: Calcium Channel Blocker (Dihydropyridine class)
- Chemical Name: 3-Ethyl 5-methyl 2-[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate
- Molecular Formula: $C_{20}H_{25}Cl\ N_2O_5$
- Molecular Weight: 408.9 g/mol
- Mechanism of Action: Inhibits L-type calcium channels in vascular smooth muscle, causing vasodilation and reduced blood pressure.
- Uses: Treatment of hypertension, chronic stable angina, and vasospastic angina
- Dosage (Adults): Starting dose 5 mg once daily; max 10 mg/day
- Absorption: High oral bioavailability (64–90%)
- Half-life: 30–50 hours (long-acting)
- Metabolism: Hepatic (mainly via CYP3A4)
- Excretion: Primarily via urine as inactive metabolites
- Common Side Effects: Peripheral oedema, dizziness, headache, flushing
- Advantages: Once-daily dosing, effective in both hypertension and angina

**2. SAMPLE COLLECTION**

**1.Amlip-5 mg**

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Figure No 18: Amlip-5mg

| | |
|---|---|
| Manufactured by: | CIPLA LTD. |
| Mfg. Lic. No.: | L/04/79 |
| Batch No.: | 4C1307 |
| Mfg. Date: | NOV 2024 |
| Exp. Date: | OCT 2027 |
| Strength | 5 mg |
| M.R.P. | 28.00rs (10 tablets) |

Table No 11: Amlip-5 Mg Details

**2.Amlip-2.5 mg**


Figure No 19: Amlip-2.5 Mg

| | |
|---|---|
| Manufactured by: | CIPLA LTD |
| Mfg. Lic. No.: | L/04/79 |
| Batch No.: | C10265 |
| Mfg. Date: | MAR 2024 |
| Exp. Date: | FEB 2026 |
| strength | 2.5 mg |
| M.R.P. | 20.04(10 tablets) |

Table No 12: Amlip-2.5 Mg Details

## 3. MATERIALS AND METHODS [14]

### Chemicals and Reagents

- **Amlodipine Besylate Reference Standard** (purity ≥99%)
- Commercial **Amlodipine tablets** (label claim: 2.5 mg and 5 mg per tablet)
- **Methanol**
- **Distilled Water**

### Preparation of Standard Solution

1. **Accurately weigh** about **50 mg** of **Amlodipine Besylate** reference standard using an analytical balance.
2. Transfer to a **50 mL volumetric flask**.
3. Add about **35 mL of methanol**, sonicate for 5 minutes to dissolve, and dilute to the mark with **methanol**.
4. This gives a stock solution of **50 µg/ml**.
5. Prepare working standard solutions by pipetting appropriate aliquots (e.g., 0.5,1,1.5,2,2.5 mL) into 10 mL volumetric flasks
6. Measure absorbance at **maximum wavelength (λmax)** of Amlodipine (~**238 nm**).

### Preparation of Sample Solution

1. Weigh and finely powder **20 tablets** of Amlodipine.
2. Accurately weigh a portion of the powder **equivalent to 50 mg of Amlodipine**
3. Transfer the powder to a **50 mL volumetric flask**.
4. Add **35 mL of methanol**, sonicate for 15 minutes to extract the drug.
5. Filter the solution using **Whatman filter paper No. 41**.
6. Wash the residue with methanol and make up the filtrate to 50 mL with methanol.
7. From this solution, pipette **5 mL** into a 50 **mL volumetric flask**, and dilute to the mark with methanol to get a **50 µg/mL** solution. And

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make dilutions in 0.5,1,1.5,2,2.5 mg/ml in 10 ml.

8. Measure the absorbance at **238 nm** against a methanol blank.

## 4. RESULTS OF ANALYSIS:

### 1.Standard aspirin

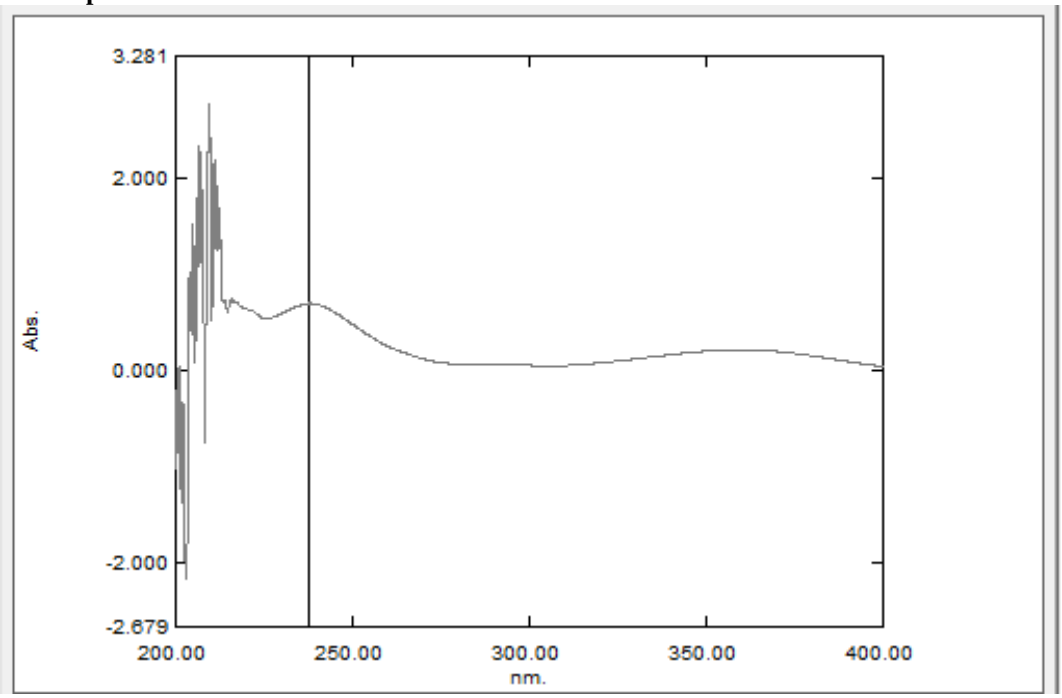
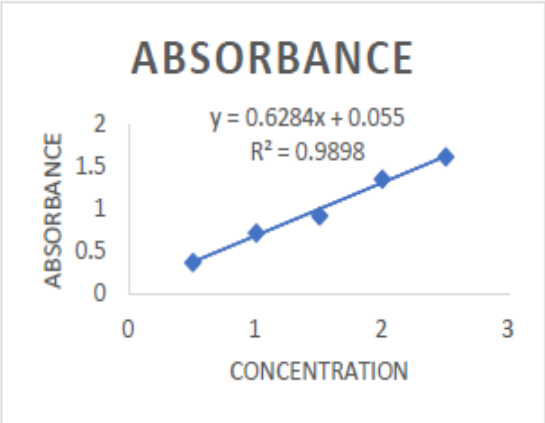



**Figure No 20: λmax of Amlodipine Standard At 238nm**

| Concentration(ug/ml) | Absorbance |
|---|---|
| 0.5 | 0.3689 |
| 1 | 0.7203 |
| 1.5 | 0.9183 |
| 2 | 1.3613 |
| 2.5 | 1.6194 |

**Table No 13: Concentration Vs Absorbance**




**Graph No 4: Calibration Curve of Amlodipine Standard**

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**2. Sample aspirin**

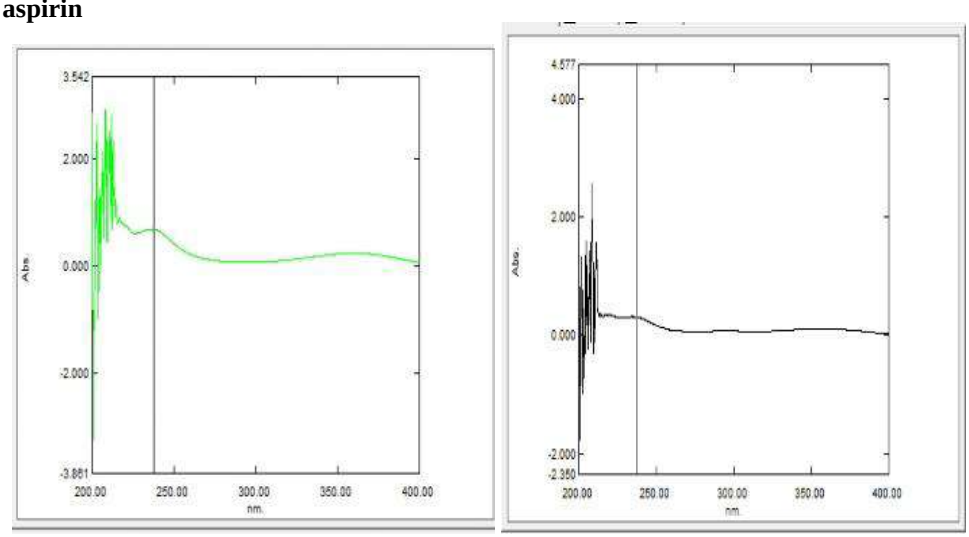


**Figure No 21: Lamda Max of Amlip 2.5 mg And Amlip 5 mg at 238 Nm**

**Formula Used:**
The calculations are based on the linear equation of the calibration curve:
**y = mx + c**, where:

- **y** is the absorbance of the sample
- **m** is the slope of the calibration curve (from standard data)
- **c** is the intercept
- **x** is the concentration of the sample (solved from the equation)
- Then, **% Purity = (Calculated Concentration / Label Claim) × 100**

**Amlodipine**
**Sample 1(5 mg):** y = 1.2929, m = 0.6284, c = 0.055
→ x = (1.2929 - 0.055) / 0.6284 = 1.96
→ % Purity = (1.96 / 2) × 100 = 98.5%
**Sample 2(2.5 mg):** y = 1.3014, m = 0.6284, c = 0.055
→ x = (1.3014 - 0.055) / 0.6284 = 1.98
→ % Purity = (1.98 / 2) × 100 = 99.2%

## II. RESULTS AND DISCUSSION:

The current research successfully employed UV-Visible spectrophotometry for the quantitative analysis of four commonly used pharmaceutical drugs Paracetamol, Ofloxacin, Aspirin, and Amlodipine in tablet formulations. The method is based on the Beer-Lambert law, which establishes a direct relationship between absorbance and concentration. Each drug's standard and sample solutions were prepared using appropriate solvents and subjected to spectrophotometric analysis at their respective maximum absorbance wavelengths (λmax): 257 nm for Paracetamol, 287 nm for Ofloxacin, 276 nm for Aspirin, and 238 nm for Amlodipine.

For each drug, calibration curves were constructed using serial dilutions of known concentrations, and the absorbance values were plotted to generate linear equations. The high correlation of linearity in each case confirmed the reliability and accuracy of the spectrophotometric method. Sample concentrations were derived by applying these linear equations, and the percentage purity was calculated using the ratio of experimentally obtained concentration to the label claim.

The study revealed slight variations in the purity of commercial tablets when compared with pharmacopeial standards. For example, Paracetamol samples showed purity levels of 95% and 101%, suggesting acceptable variability and compliance with Indian Pharmacopoeia (IP) and United States Pharmacopeia (USP) standards. Similarly, Ofloxacin samples showed purities of 95% and 105.5%, while Aspirin samples had values of 94% and 94.5%. Amlodipine, analysed through methanolic solutions, demonstrated high purity with values of 98.5% and 99.2%. All these values fall within the acceptable pharmacopeial limits, confirming the suitability of these formulations for therapeutic use.

Additionally, the method demonstrated strong applicability across different solvents—NaOH, water, ethanol, and methanol based on drug solubility, without significant loss of accuracy or

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sensitivity. The simplicity of the method, minimal sample preparation, and real-time analysis capability make it highly suitable for routine quality control in pharmaceutical industries. However, it is essential to maintain strict procedural adherence to prevent deviations due to solvent interference or instrument limitations, as discussed in the methodology.

**SUMMARY OF RESULT: -**

| Sample name | Sample no | Strength (mg) | y | m | x | c | % Purity |
|---|---|---|---|---|---|---|---|
| **Paracetamol** | Sample 1 | 650 | 1.480 | 0.5625 | 1.90 | 0.4092 | 95 |
| **Paracetamol** | Sample 2 | 500 | 1.550 | 0.5625 | 2.02 | 0.4092 | 101 |
| **Ofloxacin** | Sample 1 | 400 | 1.002 | 0.5054 | 1.9 | 0.0328 | 95 |
| **Ofloxacin** | Sample 2 | 200 | 1.0995 | 0.5054 | 2.11 | 0.0328 | 105.5 |
| **Aspirin** | Sample 1 | 150 | 0.1005 | 0.0526 | 1.88 | 0.0016 | 94 |
| **Aspirin** | Sample 2 | 75 | 0.1011 | 0.0526 | 1.89 | 0.0016 | 94.5 |
| **Amlodipine** | Sample 1 | 5 | 1.2929 | 0.6284 | 1.96 | 0.055 | 98.5 |
| **Amlodipine** | Sample 2 | 2.5 | 1.3014 | 0.6284 | 1.98 | 0.055 | 99.2 |

**Table No 14: Results Of Samples**

## III. CONCLUSION:

The present study demonstrates the effectiveness of UV-Visible spectrophotometry as a simple, accurate, and cost-efficient analytical technique for determining the percentage purity of pharmaceutical formulations. By applying Beer-Lambert's law and constructing calibration curves for both Paracetamol and Amlodipine, it was possible to quantitatively assess the concentration of active pharmaceutical ingredients in commercially available tablet formulations. The results revealed that both sample of each drug met the pharmacopeial standards specified by the Indian Pharmacopoeia (IP) and the United States Pharmacopeia (USP). The study revealed slight variations in the purity of commercial tablets when compared with pharmacopeial standards. All these values fall within the acceptable pharmacopeial limits, confirming the suitability of these formulations for therapeutic use. These findings underscore the importance of routine quality evaluation using reliable analytical techniques such as UV spectrophotometry to ensure the safety, efficacy, and regulatory compliance of pharmaceutical products. Furthermore, the study highlights the potential for this technique to be widely adopted in both research and industrial settings for the quality assurance of a variety of drug formulations.

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