"QUANTITATIVE ESTIMATION OF CIPROFLOXACIN IN MARKETED DOSAGE FORM BY USING UV- VISIBLE SPECTROSCOPY"

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ABSTRACT- The main objective is quantitative estimation of ciprofloxacin in marketed dosage form by using UV- Visible Spectroscopy. UV Spectrophotometric study was performed for the authentication of the drug. The λ max was found to be 278.0 nm and comparison with literature value authenticates the study. The absorbance was measured at 274.0 nm against a blank solution using UV-Visible Spectrophotometer. The content of Ciprofloxacin was found to be 101% (507 mg) at wavelength of 274 nm. Std. 1 shown absorbance 0.495 at 274 nm and std. 2 shown 0.295 at wavelength 274 nm. And sample solution shown absorbance 0.488 at 274 nm. Which was indicates accuracy in results. The content of Ciprofloxacin was found to in marketed dosage form of Ciprofloxacin as they claimed. The analysis result was under the limit of acceptance criteria. It may be concluded that the proposed UV spectrophotometric method can be successfully applied for the analysis of ciprofloxacin in tablet dosage forms. It is cost- effective, accurate, sensitive and reliable.

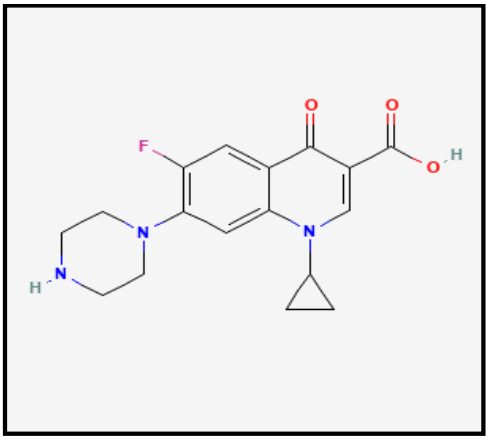
KEYWORDS- Antimicrobial, Analysis, Absorbance, Concentration, Spectrum.

INTRODUCTION- Ciprofloxacin, a second-generation fluoroquinolone antibiotic, is widely used for the treatment of a variety of bacterial infections. It has proven efficacy against a broad spectrum of Gram-positive and Gram-negative bacteria, making it a commonly prescribed drug in both inpatient and outpatient settings. As with any pharmaceutical product, the accurate quantification of ciprofloxacin in marketed dosage forms is essential to ensure both safety and efficacy. The importance of maintaining precise concentrations of active pharmaceutical ingredients (APIs) in drug products cannot be overstated, as deviations can lead to therapeutic failure or toxicity. As a result, various analytical methods have been developed to quantify ciprofloxacin in pharmaceutical formulations, among which UV-Visible Spectroscopy is one of the most widely utilized techniques due to its simplicity, reliability, and cost-effectiveness (Kumar et al., 2023). The UV-Visible spectroscopy method is based on the absorption of light by a compound at specific wavelengths. This technique is particularly useful for the analysis of pharmaceutical substances because of its non-destructive nature, ease of operation, and the ability to process a wide range of sample types, including tablets, liquids, and powders. UV-Visible spectroscopy operates by measuring the absorbance of a sample at particular wavelengths, which is directly proportional to the concentration of the compound present, following Beer-Lambert's law. This method is especially advantageous when the API in question has a strong absorbance at a particular wavelength, making it easily detectable even at low concentrations. For ciprofloxacin, a known peak is found at around 278 nm, making UV-Visible spectroscopy an ideal technique for its estimation in various dosage forms. The widespread use of UV-Visible spectroscopy in the pharmaceutical industry is also influenced by its regulatory acceptance. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have recognized UV- Visible spectroscopy as a reliable and valid method for the analysis of pharmaceutical products. Furthermore, several pharmacopoeial guidelines, such as those provided by the United States Pharmacopeia (USP), support the use of UV-Visible spectrophotometer for the quantification of ciprofloxacin in pharmaceutical dosage forms. Such regulatory backing has further reinforced the adoption of this technique in the pharmaceutical industry.

DRUG PROFILE:

CIPROFLOXACIN: Ciprofloxacin is a synthetic Antibiotic. Ciprofloxacin is an antibiotic agent in the fluoroquinolone class used to treat bacterial infections such as urinary tract infections and pneumonia. Ciprofloxacin has FDA approval totreat urinary tract infections, sexually transmitted infections (gonorrhea and chancroid), skin, bone, joint infections, prostatitis, typhoid fever, gastrointestinal infections, lower respiratory tract infections, anthrax, plague, and salmonellosis. In addition, ciprofloxacin is an appropriate treatment option in patients with mixed infections or patients with predisposing factors for Gram- negative infections.

Chemical Structure



Structure of Ciprofloxacin

Molecular Weight - 331.34 g/mol use

Chemical Formula- $C_{17}H_{18}FN_3O_3$

Mechanism of Action:
Ciprofloxacin is a bactericidal antibiotic of the fluoroquinolone drug class. It inhibits DNA replication by inhibiting bacterial DNA topoisomerase and DNA- gyrase. Of the fluoroquinolone class, ciprofloxacin is the most potent against gram- negative bacilli bacteria (notably, the Enterobacteriaceae such as Escherichia coli, Salmonella spp., Shigella spp., and Neisseria). Ciprofloxacin also has effectiveness against some gram-positive bacteria.

Mechanism of Resistance
Mutation in DNA gyrase, plasmid-mediated and efflux pump-mediated resistance confers resistance to fluoroquinolones, including ciprofloxacin. For Escherichia coli, the primary resistance mechanism is generally the GyrA subunit of gyrase.

Pharmacodynamics
Ciprofloxacin is a second generation fluoroquinolone that is active against many Gram negative and Gram positive bacteria. It produces its action through inhibition of bacterial DNA gyrase and topoisomerase IV. Ciprofloxacin binds to bacterial DNA gyrase with 100 times the affinity of mammalian DNA gyrase. There is no cross resistance between fluoroquinolones and other classes of antibiotics, so it may be of clinical value when other antibiotics are no longer effective. Ciprofloxacin and its derivatives are also being investigated for its action against malaria, cancers and AIDS.

Pharmacokinetics

Absorption: Ciprofloxacin is readily absorbed but typically does not achieve complete absorption. The bioavailability of oral ciprofloxacin is 70 to 80%. The time to peak concentrations after oral administration Tmax is 1 to 1.5 h. Avoid concurrent administration ofciprofloxacin with dairy products or calcium-fortified juices due to decreased absorption.

Distribution: The volume of distribution of ciprofloxacin is high (2 to 3 L/kg). After oral administration, ciprofloxacin is extensively distributed throughout the body. Tissue concentrations usually exceed serum concentrations, and ciprofloxacin achieves therapeutic concentrations in saliva, bronchial secretions, lymph, bile, the prostate, and urine.

Metabolism: Ciprofloxacin is an inhibitor of human cytochrome P450 1A2 (CYP1A2). Co- administration of ciprofloxacin with other drugs metabolized by CYP1A2 results in increased plasma concentrations of these drugs and could lead to toxicity.

Excretion: The elimination half-life of ciprofloxacinis4hours.Ciprofloxacin is excreted in the urine as an unchanged drug (40 to 50%). The renal clearance of ciprofloxacin is approximately 300 mL/minute, which is greater than the normal GFR of 120 mL/minute; thus, tubular secretion is the dominant process in the renal elimination of ciprofloxacin.

Administration

Ciprofloxacin is available orally, intravenously, and in topical formulations (ophthalmic and optic). Ciprofloxacin is administered orally twice daily for 7 to 14 days or at least two days after signs and symptoms of the infection are over. The recommended oral dose regimen is 250 mg twice daily to treat mild to moderate and 500 mg twice daily for severe or complicated urinary tract infections. There by for mild to moderate respiratory tract or skin and soft-tissue infections require 500mg twice-daily dosing.

Uses

Ciprofloxacin is effective in a broad range of infections. Because of wide-spectrum bactericidal activity, oral efficacy and good tolerability, it is being extensively employed for empirical therapy of any infection, but should not be used for minor cases or where gram positive organisms and/or aerobes are primarily causative. In severe infections, therapy may be initiated by i.v. infusion and then switched over to oral route.

Adverse effects

Adverse effects are mild at therapeutic doses and are mostly limited to gastro intestinal disruptions such as nausea and diarrhea. The serious adverse effects of ciprofloxacin include prolonged QT interval, hyper or hypoglycemia, and photosensitivity. Rare interactions include drug-induced bullous pemphigoid.

Result and Discussion

The pharmaceutical preparation of Ciprofloxacin tablet has following composition:

- Ciprofloxacin and Bacillus lactic acid
- In a color coated tablet formulation Color: quinoline yellow WS.
- Ciprofloxacin analysis of quantitative estimation (Quality Control) method begins with a study of **physiochemical properties** of drug substances.

Study of solubility:

Marketed drug Ciprofloxacin is showing high solubility in glacial acetic acid and poorly soluble in methanol, ethanol, chloroform and water.

Materials and Methods

- **UV Spectrophotometer: Shimadzu 1800** double beam UV/V Spectrophotometer with 1cm matched quartz cells.
- **Digital balance:** Shinko analytical balance.
- The other chemicals and glass wares were used of analytical grade from market and college.
- Ciprofloxacin was obtained from local market.

Standard Stock Solution Preparation:

- Standard stock solution of Ciprofloxacin was prepared by dissolving 10 mg of drug in 10 ml 0.1 N HCL in Volumetric flask.
- Then take1ml of prepared solution in other flask and make volume upto10ml with 0.1N HCL

Standard Serial Dilution Preparation:

- Std.1:Take1ml of stock Solution in 10ml of 0.1N HCL (10µg/ml)
- Std. – 2: Take 0.6 ml of stock Solution in 10ml of 0.1N HCL (6µg/ml)

Sample Stock Solution Preparation:

- Sample Stock Solution of Ciprofloxacin was prepared by Crushing 20 Tablets of marketed Drug into fine powder and dissolved in 10 ml of 0.1N HCL (1000µg/ml).
- Thentake1mlofpreparedsolutionin10ml0.1NHCL(10µg/ml)

Sample Serial dilution Preparation:

Take 0.1ml of stock solution of 10µg/ml and dissolved in10ml of 0.1N HCL.

Calibration curve: Spectroscopic method was performed for the prepare diluted sample solution to find out the λ max in the wavelength region 200-800 nm. The λ max standard and sample was found to be 0.495, 0.295 and 0.488 respectively. The calibration curve is plotted between the absorbance and concentration**.**

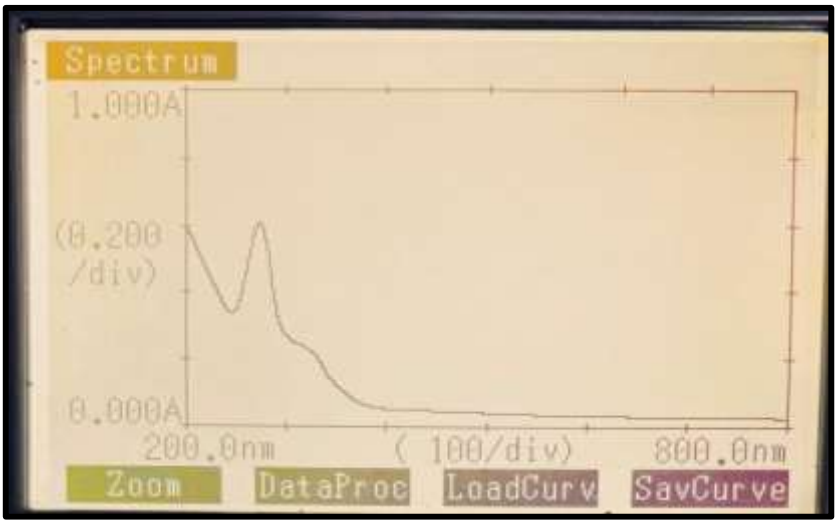
UV–Visible spectroscopy of standard & sample solution:

The spectra of UV-visible spectroscopy are plotted between concentration (Y–axis) and wavelength (X–axis). UV Spectroscopy based on the principle of Lambert and Beer law.

This law said that the absorbance of the solution is directly proportional to the concentration of absorbing substance (drug) in the solution and the path length.

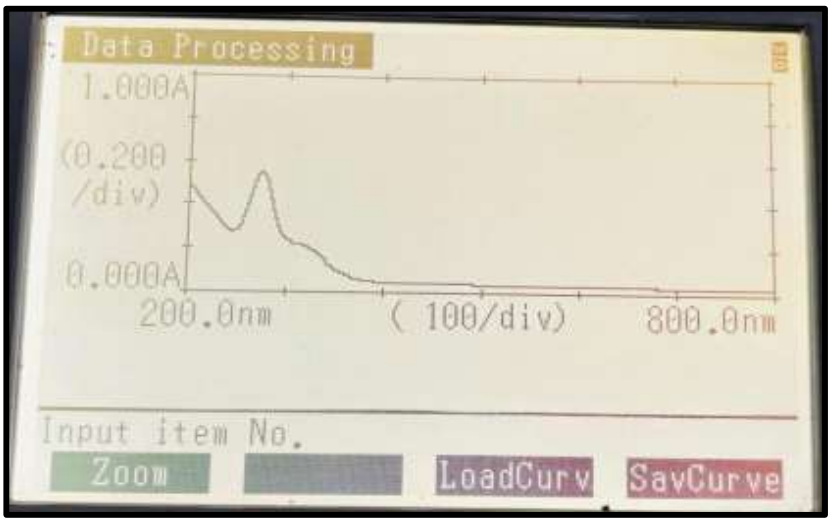
The following UV-Spectra show the λ max of standard Ciprofloxacin and sample Ciprofloxacin respective.

STANDARD DATA-1



S.No.	Conc.	Absorbance	Wavelength
Std.1	10µg/ml	0.495	274nm

STANDARD DATA-2



S.No.	Conc.	Absorbance	Wavelength
Std.2	6µg/ml	0.295	274nm

SAMPLE DATA SPECTRA

S.No.	Conc.	Absorbance	Waveength
Sample	0.8µg/ml	0.488	274nm

CALCULATION:

Actual Drug Taken = AST x Claim/ Equivalent Weight

= 0.01x500/0.511

= 9.784

$$\text{C test} = \frac{(\text{A test} - \text{A std.1})\,(\text{C std.1} - \text{C std.2}) + \text{Cstd.1}\,(\text{A std.1} - \text{Astd.2})}{(\text{A std.1} - \text{Astd.2})}$$

$$\text{C test} = \frac{(0.488-0.495)(10-6)+10(0.495-0.295)}{(0.495-0.295)}$$

$$\text{C test} = \frac{0.007x4+10x0.2}{0.2}$$

C test = 10.14µg/ml

$$\text{D. F.} = \frac{\text{Final volume}}{\text{Solute volume}} \times \frac{\text{Final volume}}{\text{Solute volume}}$$

$$\text{D. F.} = \frac{10}{0.8} \times \frac{10}{1}$$

D.F. = 125

Concentration of Solution A = D.F. into Concentration of Solution

= 10.14 x 125

= 1267.5µg/ml

%Content = testx100/10

=10.14x100/10

=101.4%

Drug in mg = 101.4x500/100

= 507mg

RESULT AND DISCUSSION:

The content of Ciprofloxacin was found to be 101% (507mg) at wavelength of 274nm. Std.1shown absorbance 0.495 at 274nm and std.2shown 0.295 at wavelength 274nm. And sample solution shown absorbance 0.488 at 274nm.Whichwasindicatesaccuracyin results.

SUMMARY AND CONCLUSION:

In this project, it was summarized that the content of Ciprofloxacin was found to in marketed dosage form of Ciprofloxacin as they claimed. The analysis result was under the limit of acceptance criteria. It can encourage the low-investing pharmaceutical companies to employ this alternative method in quality control laboratories for routine analysis of ciprofloxacin HCl. This UV Spectroscopy method was very reliable, cost effective and gave100% accuracy in results. Overall, spectroscopy is a powerful tool for the qualitative and quantitative analysis of Ciprofloxacin, ensuring its efficacy and safety in pharmaceutical applications. At the end, it was concluded that this method can be used for routine analysis of Ciprofloxacin in laboratory, college and industry in future.

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