ejpmr, 2025, 12(2), 234-238

SJIF Impact Factor 7.065

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

COMPARISON AND ASSESSMENT OF VARIOUS BRANDS OF OFF-THE-SHELF OFLOXACIN TABLETS

Jalappa Biradar*, Gulam Ayyan Gulam Zaheer, Gunthe Balaji Dnyaneshwar, Gurdale Kiran Dilip, Hembade Sanjivani Tukaram

Associate Professor, Mauli College of Pharmacy (B.Pharm) Tondar, Udgir India.

***Corresponding Author: Jalappa Biradar**

Associate Professor, Mauli College of Pharmacy (B.Pharm) Tondar, Udgir India.

Article Received on 04/12/2024 **Article Revised on 25/12/2024** **Article Accepted on 14/01/2025**

ABSTRACT

Ofloxacin, a synthetic antibiotic belonging to the second-generation fluoroquinolone class, is commonly used in chemotherapy for treating a variety of bacterial infections. It is highly effective against infections of the skin, respiratory tract, prostatitis, and mild to moderate urinary tract infections. Ofloxacin is also widely available as an over-the-counter (OTC) medication, particularly in treating bacterial infections in different parts of the body, including acute gastrointestinal infections. As a broad-spectrum antibacterial agent, Ofloxacin is active against both gram-positive and gram-negative bacteria, including *Pseudomonas aeruginosa*, *Enterobacteriaceae*, and methicillin-resistant *Staphylococcus aureus* (MRSA). This study focuses on a comparative evaluation of different commercial brands of Ofloxacin tablets to assess their quality based on various physicochemical properties. Additionally, sustained-release formulations of Ofloxacin have gained research attention in recent years, particularly with an emphasis on extending gastric retention time (GRT). Improving GRT enhances therapeutic efficacy by allowing the drug to stay longer in the stomach, leading to better absorption and prolonged effects. The ultimate goal is to improve drug delivery systems, ensuring that medications remain in the gastrointestinal tract for an extended period, thus enhancing both the therapeutic impact and patient adherence**.**

KEYWORDS: Ofloxacin tablets, Brand comparison, Pharmaceutical assessment, Drug quality analysis.

INTRODUCTION

Ofloxacin is a synthetic antibiotic classified under second-generation fluoroquinolones, widely used in chemotherapy. It plays a crucial role in treating various bacterial infections, including skin and respiratory tract infections, prostatitis, and mild-to-moderate urinary tract infections. Ofloxacin is a common over-the-counter antibiotic and anti-infective agent, utilized for bacterial infections across different parts of the body. Additionally, it is employed to manage acute gastrointestinal infections. As a fluorinated quinolone, Ofloxacin exhibits broad-spectrum antibacterial activity, proving effective against a range of gram-positive and gram-negative bacteria, including Pseudomonas aeruginosa, Enterobacteriaceae, and methicillin-resistant Staphylococcus aureus (MRSA).[1] Over the past ten years, significant research efforts have focused on developing sustained-release drug formulations, with particular emphasis on extending gastric retention time (GRT). The goal of these studies is to improve drug delivery systems by ensuring that the medication remains in the stomach for a longer duration, thereby boosting its therapeutic impact and improving patient adherence to treatment. The clinical success of an oral tablet is influenced by various factors, with the active pharmaceutical ingredient playing a crucial role in the formulation. To achieve maximum effectiveness, the drug must be available in a specific, bioactive form that the body can readily absorb. The primary purpose of an oral tablet is to deliver a controlled dose of medication through the gastrointestinal tract, ensuring it produces the desired therapeutic outcome.[2] The quantity of ofloxacin in a drug product can greatly influence various quality attributes such as weight variation, hardness, friability, disintegration time, and dissolution profile. These factors encompass not only the manufacturing processes but also the physicochemical properties of the active ingredients and excipients. Since finely sized drugs tend to compress more easily when moistened, we opted for the wet granulation method in our experiments to create controlled-release Ofloxacin matrix tablets. Ethocel derivatives were formulated in different drug-to-polymer ratios, incorporating various types and grades of the polymer, to evaluate their potential as effective matrix materials in Ofloxacin formulations.[4] A nearly constant drug release profile can be achieved through the use of controlled-release drug delivery systems, enabling the sustained maintenance of elevated drug plasma concentrations over time. Polymers are often utilized in these systems to modulate the rate of drug release,

allowing for prolonged therapeutic effects from a single controlled-release tablet and reducing the need for frequent dosing. In such matrix tablets, the drug is released through a combination of mechanisms, including degradation, diffusion, and swelling, which occur immediately following the initial diffusion phase.[4] Ciprofloxacin, along with other quinolones, exhibits a complex and not fully understood mechanism of action. These compounds are commonly referred to as "DNA gyrase inhibitors." DNA gyrase, a crucial enzyme involved in the process of DNA replication, belongs to the DNA topoisomerase family. This enzyme plays a key role in managing the supercoiling of DNA, and inhibiting its function disrupts bacterial replication, which is central to the antimicrobial effect of quinolones.[5]

OBJECTIVE

Currently, many pharmaceutical companies produce drugs for commercial use that often contain lower amounts of active ingredients than what is indicated on the label. The objective of this study is to assess the quality of various off-the-shelf brands of Ofloxacin tablets to determine whether the active ingredient in these commercial products matches the labeled dosage. Several brands of Ofloxacin tablets were evaluated, sourced from pharmacies in the Latur district, and the comparison includes different manufacturers such as Zanocin, Oflin, Oflomac, and Ofler. Each tablet contains 200 mg of Ofloxacin, and various quality attributes such as weight variation, hardness, friability, disintegration time, and dissolution profile were evaluated to determine the overall quality of the products.

MATERIALS

Five different brands, including Zanocin, Oflin, Oflomac, and Ofler, were sourced from pharmacies in the Latur district and labeled as 1, 2, 3, and 4, respectively, to conduct a comparative evaluation of various paracetamol brands. Each tablet from the selected brands contains 200 mg of ofloxacin. While all the brands have a listed shelf life of three years from the manufacturing date, the tablets used for research were set to expire two years from the start of the study. (Table 1).

SR. NO	BRAND NAME	MANUFACTURED BY	DOSE
1	Zanocin	SUN Pharmaceutical Industries Ltd	200 mg
2	Oflin	ZYDUS Cadila	200 mg
3	Oflomac	MACLEODS Pharmaceuticals Pvt Ltd	200 mg
4	Ofler	ARISTO Pharmaceuticals Pvt Ltd	200 mg

EQUIPMET USED

A High Precision Balance was used to assess weight variation, while Vernier Calipers measured tablet thickness. The hardness of the tablets was evaluated using a Monsanto Hardness Tester, and friability was tested using a Roche Friabilator. For dissolution studies, the USP Dissolution Apparatus was employed, and tablet disintegration was measured with the USP Disintegration Apparatus.

Evaluation parameters of ofloxacin tablets[6,7,8,9]

Thickness

Tablet thickness must be maintained within a ±5% deviation from the specified value to ensure uniformity. Any variations in thickness, whether between different manufacturing batches or within the same batch, should not be noticeable to the naked eye to maintain product quality and customer satisfaction. The thickness of the tablets was measured using Vernier Calipers, with the target thickness calculated to fall within the range of 3.5 to 4 mm.

Hardness

Tablet hardness refers to the amount of force required to break a tablet when pressure is applied diametrically. This force is measured by placing the tablet between two anvils and applying pressure until the tablet fractures, which provides its crushing strength, another term for hardness. The hardness of the tablets was evaluated using a Monsanto hardness tester, which consists of two plungers and a barrel containing a spring. The process begins by touching the tablet with the lower plunger to establish a zero reading. A threaded bolt is then rotated, pushing the upper plunger against the spring, causing the tablet to break. As the spring compresses, a pointer moves along a gauge in the barrel, indicating the applied force. The force recorded at the point of fracture provides the tablet's hardness, with an ideal range set between 2 and 4 kg/cm².

Weight Variation Test

To guarantee that each tablet contains the correct amount of active ingredient, the weight of the tablets is routinely monitored during production. When formulating tablets, a specific quantity of medication is incorporated into a precise amount of the tablet formulation. For this study, the individual and average weights of 20 tablets were recorded. A weight variation of up to 7.5% is considered acceptable. According to the USP standards, the batch passes the test as long as no tablet exceeds double the permissible percentage variation or deviates by more than twice the acceptable limit.

$$\text{Weight Variation Test} = \frac{\text{Weight of tablet} - \text{Avg.weight of tablet}}{\text{Avg.weight of tablet}}$$

Friability

A Roche friabilator is employed in the laboratory to evaluate the friability of tablets. This device consists of a plastic chamber that rotates at 25 revolutions per minute,

dropping the tablets from a height of six inches. The friabilator operates for a total of 100 revolutions. After this process, the tablets are weighed again to assess any weight loss. Tablets that retain 99.5% to 99.0% of their original weight following this test are considered acceptable.

Disintegration Test (U.S.P.)

The U.S.P. disintegration testing apparatus features six three-inch glass tubes, each with an open top and a mesh screen at the bottom. To determine the disintegration time, a single tablet is placed in each tube, and the entire assembly is positioned in a one-liter beaker filled with water, simulated gastric fluid, or simulated intestinal fluid, maintained at a temperature of 37 ± 2 °C. During testing, the tablets must remain 2.5 cm below the liquid surface as they are lifted and should not touch the bottom of the beaker during the downward phase. The basket, containing the tablets, is then moved up and down over a range of 5 to 6 cm at a frequency of 28 to 32 cycles per minute. For the test to be valid, the tablets must completely disintegrate into particles.

Dissolution Test (U.S.P.)

A single tablet is placed inside a small wire mesh basket attached to the bottom of a shaft, which is linked to a motor capable of variable speeds. This basket is submerged in a 100 ml flask containing a dissolution medium, as specified in the monograph. The flask, which features a cylindrical shape with a hemispherical bottom, is maintained in a temperature-controlled bath set at 37 ± 0.5°C. To determine the concentration of the active ingredient in the solution, the motor is adjusted to operate at a predetermined speed, allowing for the withdrawal of fluid samples at specified intervals.

RESULTS AND DISCUSSION

Evaluation of Characteristics

Tablet's physicochemical characteristics: Tablets are evaluated for several key parameters, including weight variation, thickness, hardness, friability, and disintegration time. The results of these assessments are summarized in the table below.

Table No 2: Physical evaluation of different 'B' brands of Ofloxacin tablets.

Sample (Tablet Brands)	Weight variation test limit (%)	Hardness (kg/cm²)	Friability (%)	Disintegration Time (min/sec)	Thickness (mm)
B1	1.91±0.04	7.55±0.05	0.35±0.02	4.46±0.08	3.4mm
B2	1.30±0.05	6.45±0.34	0.68±0.35	4.39±0.15	3.7mm
B3	1.30±0.05	5.75±0.34	0.29±0.35	4.27±0.15	3.1 mm

Table No. 3: Physical evaluation of different 'B' brands of Oflxaicn tablets.

Sr.no	PHYSICAL PARAMETER	B1	B2	B3
1	Weight variation	1.49±0.05	1.91±0.04	1.70±0.15
2	Thickness	3.9mm	4.1mm	3.6mm
3	Hardness	5.43±0.34 kg/sq.cm	4.45±0.10 kg/sq.cm	6.46±0.34 kg/sq.cm

Table No 4: Dissolution Profile for brand B1 in 0.1 N HCl.

Sr.no	Time(min)	%Drug dissolvoed
1	2 hrs	0.25 ± 0.09

Table No 5: Dissolution profile for brand B1 in pH 6.8 phosphate buffer.

Sr.no	TIME (min)	% Drug dissolved
1	0	0
2	5	16± 0.14
3	10	20±0.07
4	15	28±0.19
5	30	36±0.14
6	45	53±0.15
7	60	73±0.19

Table No 6: Dissolution Profile for brand B2 in 0.1 N HCl.

Sr.no	Time(min)	%Drug dissolvoed
1	2 hrs	**39. ± 0.14**

Table No 7: Dissolution profile for brand B2 in pH 6.8 phosphate buffer.

Sr.no	TIME (min)	% Drug dissolved
1	0	0
2	5	19± 0.15
3	10	27±0.03
4	15	38±0.19
5	30	49±0.09
6	45	63±0.14
7	60	83±0.18

Table No 8: Dissolution Profile for brand B3 in 0.1 N HCl.

Sr.no	Time(min)	% Drug dissolvoed
1	2 hrs	48± 0.06

Table No 9: Dissolution profile for brand B3 in pH 6.8 phosphate buffer.

Sr.no	TIME (min)	% drug dissolved
1	0	0
2	5	19± 0.15
3	10	42±0.03
4	15	53±0.19
5	30	61±0.09
6	45	74±0.14
7	60	88±0.18

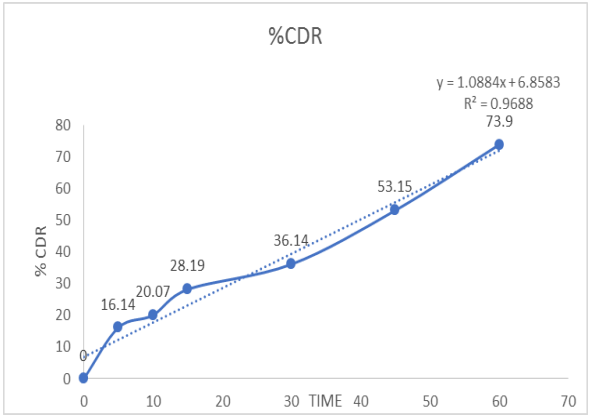

Figure No. 1: Drug Release profile for brand B1 in pH 6.8 Phosphate buffer.

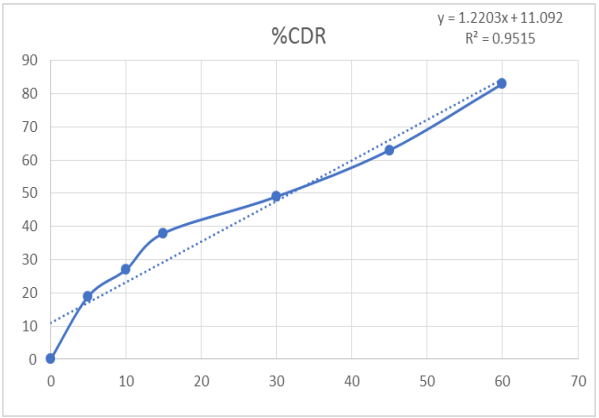

Figure No. 2: Drug Release profile for brand B2 in pH 6.8 Phosphate buffer.

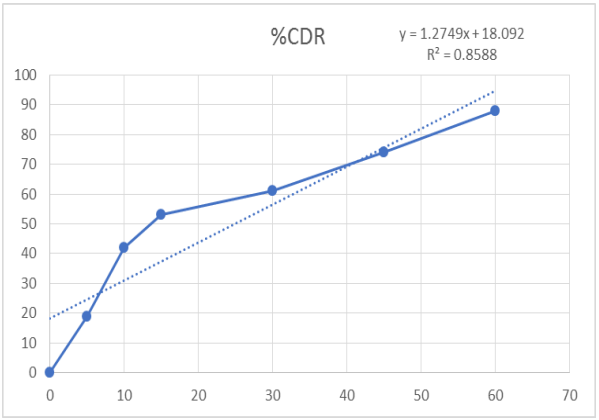

Figure No. 3: Drug Release profile for brand B3 in pH 6.8 Phosphate buffer.

DISCUSSION

For safe handling and transportation, all of the brands showed good hardness and strength. While the hardness of all the other brands was comparable, Brand 3 showed the highest level of hardness. The friability of each brand was less than 2%. Tablets with low friability values are those that don't tend to powder when handled and transported. Every brand of tablet included the appropriate amount of Ofloxacin, according to U.S.P. guidelines. The weight variation test was passed by every brand of pill. I.P. states that if the tablets have a consistent weight, it is probable that the drug content will be consistent as well. Therefore, I.P. only recommends weight variation testing for tablets when the medication makes up the majority of the pill. Given that every brand passed the weight variation test, it can be said that the medication content of every tablet is consistent. The U.S.P. disintegration test was passed by all pill brands, meaning that they will all dissolve in the colon in two hours but not in the stomach. As directed by the U.S.P., every brand of pantoprazole pill passed the disintegration test. The U.S.P.-recommended dissolution test was passed by all brands, but the pace at which pantoprazole dissolved varied amongst the.

CONCLUSION

Every brand passed all official tests and complied with all Pharmacopoeia criteria. Every brand performed within the permitted range when measured for thickness, weight fluctuation, hardness, friability, and other characteristics. Comparing the amount of medication obtained to the labeled claim, the percentage purity and amount obtained are lower. The reason for the variance in the observed dissolving profiles is due to different formulation ingredients in the tablet, different manufacturing procedures, and different drug forms employed in the tablet.

REFERENCES

1. Smythe, Maureen A., and Michael J. Rybak. "Ofloxacin: A Review." *DICP*, Nov. 1989; 23(11): 839–846, https://doi.org/10.1177/106002808902301101
2. FORMULATION AND EVALUATION OF OFLOXACIN FLOATING TABLETS USING HPMC.
3. Mistry, Amisha K. "Formulation and in Vitro Evaluation of Ofloxacin Tablets Using Natural Gums as Binders." *Scientia Pharmaceutica*, 2014; 82(2): 441–448. https://doi.org/10.3797/scipharm.1401-14.
4. Shah, Shefaatullah, et al. "Formulation and in Vitro Evaluation of Ofloxacin-Ethocel Controlled Release Matrix Tablets Prepared by Wet Granulation Method: Influence of Co-Excipients on Drug Release Rates." *PubMed*, 1 July 2011; 24(3): 255–61. Accessed 9 Oct. 2024.
5. LeBel, Marc. "ofloxacin: Chemistry, Mechanism of Action, Resistance, Antimicrobial Spectrum, Pharmacokinetics, Clinical Trials, and Adverse

Reactions." *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*, 2 Jan. 1988; 8(1): 3–30. https://doi.org/10.1002/j.1875-9114.1988.tb04058x

6. Banker, Gilbert S. "The Theory and Practice of Industrial Pharmacy." *Journal of Pharmaceutical Sciences*, Oct. 1970; 59(10): 1531. https://doi.org/10.1002/jps.2600591046. Accessed 20 Nov. 2019.
7. "The Theory and Practice of Industrial Pharmacy. Leon Lachman, Herbert Lieberman, and Joseph Kanig, Editors." *The Journal of Clinical Pharmacology and the Journal of New Drugs*, 12 Nov. 1970; 10(6): 420–420. https://doi.org/10.1177/009127007001000614. Accessed 5 Mar. 2023.
8. Indian Pharmacopoeia, The Controller of Publications, Delhi, 1996; 1: 735.
9. Aulton, Michael E, et al. *Aulton's Pharmaceutics*. Edinburgh Etc., Churchill Livingstone/Elsevier, 2015.