



RESEARCH ARTICLE

Journal home page: www.jpadr.com

Analysis of price variation & formulation aspects of different brands of cefixime marketed in NCR region

Aditya Kaushal ^a, Saurabh Saraswat ^b, Manvi Aggarwal ^{c,*}, Ankit Sharma ^a

^a B.Pharm(Student), Department of Pharmacy, School of Health Sciences, Sushant University, Gurugram-12203, Haryana, India

^b Associate professor, Department of Pharmacy, School of Health Sciences, Sushant University, Gurugram-12203, Haryana, India

^c Assistant professor, Department of Pharmacy, School of Health Sciences, Sushant University, Gurugram-12203, Haryana, India

ARTICLE INFO ABSTRACT



Received 04 December 2023;
Revised 21 January 2024;
Accepted 20 February 2024.

Keywords:

Dissolution,
Disintegration, Friability,
Hardness & Defects

Introduction: Cefixime tablets are frequently recommended by doctors to cure bacterial infections. Cefixime tablets are commonly prescribed to treat bacterial infections. This antibiotic medication can work either as bacteriostatic or bactericidal. In the NCR region,

Aim & Objective: To identify the Price Variability Among certain brands of Cefixime available NCR region

Method: Eight different brands of Cefixime tablets opt for quality control testing. Each brand was subjected to various tests, including evaluation for defects, friability, hardness, disintegration, and dissolution. In total, 10 tablets were tested for each brand to ensure their quality.

Result: Each brand has less than 1% acceptable friability values, except AricefO and Cefilab. Each brand represents hardness values around 8 to 13 N. No defects have been detected in any of the brands. The disintegration and dissolution tests were also tested, performed, and identified.

Discussion: The quality of medicines must be re-evaluated it is run by the regulatory body responsible for ensuring the safety and effectiveness of medicines people use throughout their shelf life.

An official publication of the Global Pharmacovigilance Society.

Introduction

Certain bacterial diseases, including a sexually transmitted illness i.e. gonorrhoea, infection of the airway tubes leading to the lungs i.e. bronchitis, and infections of the tonsils, ears, throat, and urinary system, can be treated with cefixime (Tsabang et al., 2016). Cefixime belongs to a group of drugs known as cephalosporin antibiotics. It functions by eradicating bacteria. For colds, the flu, or other viral diseases, it is ineffective. The chance of developing an infection later on that is resistant to antibiotic therapy rises when you use antibiotics when

they are not necessary. Cefixime is available in a liquid swallow, chewable tablet, capsule, and tablet form. Usually, it is taken every 12 or 24 hours, with or without food. It can be used as a single dosage to treat gonorrhoea. Take cefixime daily at approximately the same times. The instructions are written on the prescription and contact your pharmacist to explain anything you don't understand. Administer cefixime as prescribed. Never take more or less of it, or take it more frequently than your doctor has instructed. For the medication to be



* Corresponding Author

Manvi Aggarwal

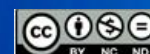
E-mail: manvi0502@gmail.com

Contact: +917015923851

* Copyright: 2582-7235 // © 2024 The Author(s).

Published by Global Pharmacovigilance Society.

This is an open-access article under the CC BY-NC-ND license.



Available online 1 June 2024

evenly mixed, shake the mixture thoroughly before using. When taking chewable tablets, make sure you chew them thoroughly before swallowing; avoid swallowing the chewable tablets whole. You can crush them before swallowing if you have problems chewing. Cefixime pills have a line running through the centre of them. Should your physician advise you to take half a tablet, carefully break it open on the phone. As instructed, take half of the tablet, and reserve the other half for your subsequent dose. Cefixime products cannot be swapped for one another since the body absorbs them in distinct ways. Your doctor may need to change your dose if you need to move from one cefixime medication to another. It is within the first few days of cefixime medication that you should start to feel better. Contact your physician if your symptoms do not get better or if they worsen. Even if you start feeling better, keep taking cefixime. Cefixime may not fully treat your infection and the bacteria may develop antibiotic resistance if you stop taking it too soon or miss doses. (Evariste et al., 2016)

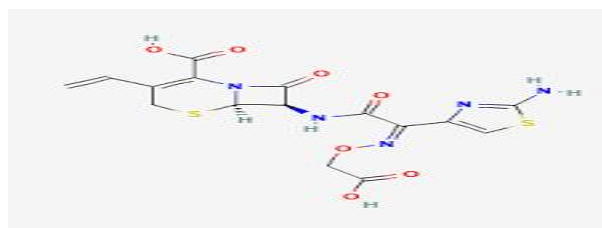


Figure 1: Structure of Cefixime

Aim & Objective

- To identify the Price Variability Among certain brands of Cefixime available NCR region
- To identify the percentage variation in price.
- Comparison of brands of Cefixime sold in the NCR region

Eight brands of cefixime were purchased from pharmacies in the NCR region. For various quality control measures, 10 tablets of cefixime per drug were selected to obtain readings. The qualities of the

Products are checked by performance tests and certified according to Indian Pharmacopoeia standards. Analysis of variable costs of different brands of cefixime in the NCR region was conducted in Table 1. (Evariste et al, 2016)

Table 1: Different brands of cefixime with their company & source.

Brand	Company	Source
GENERIC(C1)	CIPLA	Mohalla Clinic
ZIFI(C2)	Fdc Ltd	Retail Shop

TAXIM-O(C3)	ALKEM LAB	Retail Shop
HACEF(C4)	MANKIND	Retail Shop
ARICEF O(C5)	MICRO LABS	Retail Shop
SUPRAX(C6)	Health kind labs	Retail Shop
Cefspan(C7)	Fujisawa Pharma	Online
Cefilab(C8)	Malik life science	Retail Shop

The following tests were performed:-

- 1.Dissolution test
- 2.Disintegration test
- 3.Friability test
- 4.Hardness test
- 5.Visualization of defects

Methodology

Dissolution test

Making of Buffer Solution

Add 175 ml 0.2 M NaOH to 250 ml 0.2 M dipotassium hydrogen orthophosphate (K₂HPO₄) and dilute to 1000 ml distilled water. Later buffer solution should be set by the use of 0.5 HCl up to 5.8 ph.

The procedure involves preparing a dissolution medium that mimics the physiological conditions of the gastrointestinal tract, such as pH and temperature. The test is typically conducted using a dissolution apparatus, such as the ISP paddle method, which maintains the medium at a constant temperature with constant stirring. A sample was kept in the apparatus, and samples were withdrawn at specified time intervals. The quantity of the drug dissolved is then measured using a suitable analytical method, such as UV spectrophotometry, and compared against predetermined acceptance criteria to obtain the drug's dissolution characteristics in Table 2. (Nobuyuki et al., 2019)



Figure 2: Dissolution apparatus

Disintegration test

The disintegration test, according to Indian Pharmacopoeia (IP), is performed to identify the time it takes for tablets or capsules to disintegrate into smaller particles under specified conditions. The procedure involves placing six tablets or capsules in each of the six tubes of the disintegration test apparatus, ensuring they are evenly spaced and not in contact with each other. The tubes are then filled with a specified medium, typically a suitable liquid as per the pharmacopoeial monograph. The assembly is placed in a water bath at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ or another specified temperature. The tablets or capsules are observed, and the time taken for complete disintegration is recorded. The test is considered complete when all six tablets or capsules have disintegrated, or when the specified time limit has been reached as shown in Table 3. (Kamimura et al., 1984).



Figure 3: Disintegration apparatus

Hardness Test

Identifying hardness requires randomly choosing 20 tablets from each brand tested using the hardness tester mentioned above in Table 5. (Shah Zubin et al., 2001).



Figure 4: Monsanto

Friability Test

Friability testing is closely related to tablet hardness and binder concentration. Tablets with a unit size of 200 mg were used to obtain the friability test

according to IP. Choose ten. Take the tablets and spin the m 100 times at 25 rpm. Remove the solution and reweigh itto determine the percent friability for each species. The weight of the tablet must be less than or equal to 1% as shown in table 4. (Singal et al., 2011)



Figure 5: Friability tester

Results

The result of the Dissolution test in Table 2

Table 2: Readings of Dissolution parameter

Time	C1	C2	C3	C4	C5	C6	C7	C8
15 min	75.02	71.87	78.07	73.61	71.56	76.12	70.89	72.00
30 min	81.10	87.12	85.01	89.77	85.09	81.28	79.09	84.99
45 min	98.00	94.54	80.88	95.00	95.54	90.33	89.44	92.42

Generic brands and Cefspan brands took less time to dissolve.

Table 3: The result of the Disintegration test

Brand	Time (Seconds)
C1	35
C2	37
C3	40
C4	31
C5	38
C6	33
C7	40
C8	29

Taxim-O and Cefspan have higher Disintegration time

Table 4: Result of the Friability test

BRAND	Initial weight	Final weight	Friability (%)
C1	3.32	3.30	0.60%
C2	3.28	3.28	Nil
C3	3.42	3.41	0.29%
C4	3.29	3.28	0.30%
C5	3.09	3.05	1.29%
C6	3.15	3.14	0.31%
C7	3.27	3.25	0.61%
C8	3.10	3.04	1.93%

The friability of Cefilab is highest i.e. 1.93%

Table 5: The result of the Hardness test

S.No	Brand	Hardness
1	C1	8.50N
2	C2	11N
3	C3	9.50N
4	C4	11N
5	C5	10.6N
6	C6	11N
7	C7	13N
8	C8	10.2N

Cefspan has the highest value in Hardness.

Table 6: Result of defects

Brand	Blistering	Chipping	Blooming	Blushing	Cracking
C1	NO	NO	NO	NO	NO
C2	NO	NO	NO	NO	NO
C3	NO	NO	NO	NO	NO
C4	NO	NO	NO	NO	NO
C5	NO	NO	NO	NO	NO
C6	NO	NO	NO	NO	NO
C7	NO	NO	NO	NO	NO
C8	NO	NO	NO	NO	NO

No Defects have been noticed.

Discussion

Dissolution Test

This is the importance of quality control. It is related to the bioavailability of the drug.

This study found that after 45 minutes, the release of various types of cefixime was satisfactory, ranging from 70% to 99%. C1 showed the highest drug release percentage, while C7 achieved the lowest value. Differences in product release may result from improper mixing. During the manufacturing process, pure chemicals are mixed with various additives such as dyes, diluents, granulating agents, binders & lubricants the rate of dissolution will change.

Additionally, the granulation method and force of compression can affect the fracture rate.

Disintegration Test

Disintegration time is the time required for the tablet to break into smaller pieces and then completely dissolve the drug in the body. This test clarified that all brands displayed satisfied disintegration time with an average range from 29 to 40 seconds. It showed the shortest time of 29 seconds, while the longest time was achieved by C3 & C7 with an average time of 40 seconds. Hence there was a difference between these brands.

Hardness Test

Tablet durability is important to measure the tablet's ability to withstand mechanical damage. In this study, the crushing strength of C2, C4, and C7 was found to be lower than 15N, which is an acceptable value.

At the same time, the breaking force of other types is higher than 8N, and C7 represents the highest value. Variations in results may be related to the design or manufacturing process used in preparing the tablets, such as the compression force, the amount of material used (more binder becomes stronger again), and the granulation method. If the hardness value is higher, the disintegration time should be tested before rejecting the batch. If it is within the limit, the party is accepted. Therefore, there are significant differences between brands.

Friability Test

The ability of tablets to prevent damage during packaging and handling can be checked by friability testing. Current research shows that most brands have a reasonable fragility between 0.59% and 1.54%. The results obtained follow the IP standard ($\leq 1\%$) with results ranging from 0.59% to 1.54%. The reason for this high price may be increased tablet breakage due to many factors such as compression force, binders,

and additives used in production. The compression force and binder concentration must be adjusted to prevent tablet strength values from becoming too high or too low. Therefore, there are no significant differences between species.

Defects test

For visualizing the defects we visualized the following parameters i.e. Blistering, Blooming, Chipping, Capping, and Blushing. We didn't find any defect in any tablet as shown in Table 6.

Conclusion

The quality of medicines must be re-evaluated it is run by the regulatory body responsible for ensuring the safety and effectiveness of medicines people use throughout their shelf life. Cefixime is the most prescribed drug by doctors and is known for its antibacterial action. This study aims to evaluate eight different brands of cefixime tablets available in the NCR region. However, eight different types of cefixime were tested. Therefore, research shows that the results of most types of tests are reliable.

Reference

- Kamimura, T., Kojo, H., Matsumoto, Y., Mine, Y., Goto, S., & Kuwahara, S. (1984). In vitro and in vivo antibacterial properties of FK 027, a new orally active cephem antibiotic. *Antimicrobial agents and chemotherapy*, 25(1), 98–104.
- Kitamori, N., Iga, K. (1978). Dissolution Profiles of Drugs from Tablets, *Journal of Pharmaceutical Sciences*, 67(10), 1436–1439.
- Kojo, H., Shigi, Y., & Nishida, M. (1980). A novel method for evaluating the outer membrane permeability to beta-lactamase-stable beta-lactam antibiotics. *The Journal of antibiotics*, 33(3), 310–316.
- Matsumoto, Yoshimi & Kojo, Hitoshi & KAMIMURA, TOSHIKI & MINE, YASUHIRO & Goto, Satoshi & NISHIDA, MINORU & Kuwahara, Seiji. (1985). The mechanism of action of cefixime, a new oral cephalosporin. *CHEMOTHERAPY*. 33. 123-133.
- Patel, D. & Thiyagu, Rajakannan & Mallayasamy, Surulivelrajan & Patel, Heenaben & Pandey, Sujeet. (2009). Price variability among the oral antibiotics available in a South Indian Tertiary Care Hospital. 3. 1871-1875.
- Pathak, P., & Dawane, J. (2016). In vitro Comparison of Generic and Branded Preparations of Amoxicillin with Potassium Clavulanate. *Journal of clinical and diagnostic research : JCDR*, 10(9), FC07–FC09.
- Shah, Z., Dighe, A., Londhe, V. (2015). Pharmacoeconomic study of various brands of antibiotic medications in India. *World Journal of Pharmaceutical Research*, 4(3), 1600-1606.
- Singal, G. L., Nanda, A., & Kotwani, A. (2011). A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India. *Indian journal of pharmacology*, 43(2), 131–136.
- Tsabang, N., Evariste, F., Adamou, B., Bernard, D., Néhémie, D. T., Alembert, T. T., Gabriel, A., Francois, Z., & Benoit, N. T. (2016). Ethnopharmacological studies for sustainable development in Cameroon. *Research & Reviews: Journal of Pharmacy and Pharmaceutical Sciences*, 5(3), 38-56.
- World Health Organization..(2012)– Safety monitoring of medicinal products. Reporting system for the general public.Retrieved from <https://www.who.int/publications/i/item/9789241503198>
- Yang, P., Fujimura, S., Du, Y., Zhang, B., Yang, L., Kawamura, M., Zhang, Z., & Zhai, S. (2021). Comparison of Pharmaceutical Characteristics between Brand-Name Meropenem and Its Generics. *Antibiotics (Basel, Switzerland)*, 10(9), 1096.
- Zimmermann, W., & Rosselet, A. (1977). Function of the outer membrane of *Escherichia coli* as a permeability barrier to beta-lactam antibiotics. *Antimicrobial agents and chemotherapy*, 12(3), 368–372.