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IN-VITRO EVALUATION OF QUALITY CONTROL PARAMETERS OF PIROXICAM TABLETS MARKETED IN INDIA

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Abstract:
Analgesic and antipyretic, piroxicam is typically used to treat osteoarthritis and rheumatoid arthritis by lowering temperature and relieving pain. Currently, every pharmaceutical company uses a different manufacturing process and technology to make different types of piroxicam pills. The study's objective is to assess and compare many kinds of 20 mg piroxicam tablets. Fiveb distinct brands of 20 mg piroxicam tablets were chosen for this study from nearby marketplaces in India and examine their quality control measures, such as disintegration and dissolution tests, hardness, friability, and weight variation.The test results for all four brands of piroxicam l tablets were found to be within acceptable bounds; the weight variation was found to be within ±5% of the average weight, and the friability was found to be less than 1%. The disintegration time for each brand of piroxicam tablet was found to be within three minutes, and the percentage release of all brands of piroxicam tablets was found to be not less than 85%. IP specification limit in less than half an hour. Thus, we concluded that, with the exception of price, all piroxicam tablets from various manufacturers are safe and effective to use.

Key Words:*piroxicam, analgesic , antipyretic, comparative study.*

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INTRODUCTION:

A non-steroidal anti-inflammatory medication with analgesic and antipyretic properties, piroxicam is frequently given. N-heterocyclic carboxamide is its chemical name. 1,2 benzothiazine 1,1 dioxide is the source of piroxicam. Known for its analgesic and anti-inflammatory properties, the relatively new 4-hydroxy-1,2 benzothiazine carboxamide enolic acid class was given the name oxicam. Piroxicam is used to relieve the pain brought on by inflammatory illnesses like arthritis. It belongs to the oxicamclass of nonsteroidal anti-inflammatory medicines (NSAIDs).

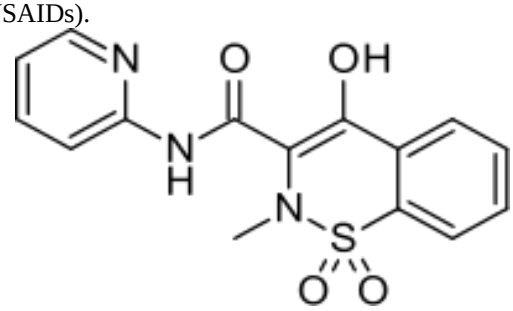

Fig no:1 Stucture of piroxicam

Piroxicam works by preventing the body from producing endogenous prostaglandins, which are involved in the mediation of pain, stiffness, soreness, and swelling. Piroxicam is a crystalline powder that is white or slightly yellow in color. It is soluble in methylene chloride, soluble in water, and slightly soluble in ethanol. Piroxicam is well, absorbed when administered orally. The relative bioavailability values as the ratios of mean total AUC for GL relative to PP and CD, were 221 and 98.6%. The crystalline powder known as piroxicam is either white or slightly yellow in hue. It dissolves in water, methylene chloride, and ethanol, although only slightly. Oral piroxicam administration results in good absorption. The mean total AUC ratios for GL in relation to PP and CD were 221 and 98.6%, respectively, representing the relative bioavailability values. "Quality is a totality of features and characteristics of a product or service that bears its ability to satisfy stated or desired needs," states the International Organization for Standardization (ISO) definition. The assortment of attributes that enable a tablet to satisfy specific pharmacopeial requirements is what makes it high-quality. It's possible that patients lack the specific expertise necessary to determine if the product they're utilizing is high-quality or not. WHO (2017) reports that the frequency of counterfeit medications was higher in poor nations with lax enforcement, few laws, limited supplies of necessary medications, an unregulated market, and exorbitant costs.8 These factors make it impossible to guarantee the safety, effectiveness, and quality of pharmaceutical products, particularly in developing nations; for this reason, post-market qualitative research is crucial. Research has been done on the quality assessment of piroxicam in many nations; it is the most commonly used medicine for treating rheumatoid arthritis and osteoarthritis. Piroxicam is a chemically unique, long-acting, potent anti-inflammatory and analgesic medication that is currently available in more than 80 countries worldwide for the treatment of arthritis and other inflammatory disorders. A single generic medication is typically produced under several brand names by various businesses. The medication is also produced on a modest basis in several nations, where it may be consumed locally or extensively distributed. Even yet, a single generic medication sold under many brand names and produced by various companies should meet all pharmaceutical requirements. Variations in pharmacological parameters have a discernible effect on the drug's therapeutic efficacy, potentially leading to an unexpected outcome. Treatment failure and drug resistance may result from improper quality control procedures or from the active ingredient in the drug dosage form breaking down in the drug's dosage form due to excessive storage temperatures and humidity. The purpose of this study was to assess the quality of piroxicam tablet brands that are commonly sold in the Indian market.

METHODS AND MATERIALS:

Study Design:

The in-vitro quality control parameter of the commercially available piroxicam tablet brands that are available in the Indian market was assessed using the experimental in-vitro study design. A variety of quality-related test procedures, including weight variations, hardness, friability, disintegration time, dissolution profile, and content uniformity of drug release, were carried out during the investigation.

Instruments:

The following instruments were employed: a UV spectrophotometer, an analytical balance, a tablet hardness tester, a thickness tester, a friabilator, a disintegration tester, and a dissolution test instrument.

Sample Collection:

Five widely used brands of piroxicam - DT, each with a 20 mg dosage claim, were gathered from Indian private pharmacies. For the analysis, roughly 100 piroxicam tablets from each brand were gathered. Product details include the name of the manufacturer,

the manufacturing date, the expiration date at the time of purchase, and each brand's unique code.

Methods:
The assessment of every brand of 20 mg piroxicam tablet used in this investigation involved the execution of the subsequent in vitro quality control procedures.

Visual inspection:
Different tablet brands' visual characteristics, including shape, size, and color, were noted. A Vernier caliper was used to measure the thickness of tablets (selected at random), and a Monsanto hardness tester was used to determine the tablets' hardness.

Hardness test:
From each brand, twenty tablets were chosen and put through the Monsanto hardness testing. By pushing the screw knob forward, the force exerted to the tablet's edge was progressively raised until the tablet broke, and the pressure at which each tablet crushed was noted. For every brand, the mean and hardness were determined.

Thickness test:
Using a Vernier caliper, the thickness of ten tablets per brand was measured for the thickness test, and the average values of each brand were computed.

Weight Variation Test:
From each brand, twenty tablets were chosen at random and weighed separately on an analytical scale. For every brand, the mean and standard deviation were determined. Subsequently, the weight variation percentage was calculated by the following formula:

$$\% \text{ of weight variations} = \frac{\text{Average weight} - \text{Initial weight}}{\text{Average weight}} \times 100$$

Friability:
Twenty tablets were chosen for each brand, properly dusted, and weighed before testing. After that, the tablets were put inside the friability tester's drum and spun for four minutes at a speed of 25 rpm. Tablets were reweighed after 100 revolutions and dedusting, and the following formula was used to determine the friability percentage:

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Disintegration test:
Examine Six tablets from each brand were chosen at random and put into the disintegration device, which has 900 ml of distilled water (the disintegration medium) in it and is kept at 37±1°C. The amount of time required to break down the tablet and go through the mesh was noted, and the average amount of time was calculated.

Dissolution Test:
Indian Pharmacopeia was followed while conducting the dissolving test. Potassium phosphate (pH 5.8) was used to create a buffer, which was kept at 37 ±1°C for the duration of the experiment. After 5, 10, 20, 30, 45, and 60 minutes, the samples were removed, and a fresh batch of buffer solution was added in their place right away. After filtering the samples, a UV spectrophotometer was used to measure the absorbance at 243 nm in order to determine the drug content of the samples. As a blank, phosphate buffer was employed.

Results:
The brands that were the subject of the study, which focused on well-known piroxicam bands marketed in India, are presented in Table 1. The results of visual properties including colour, shape, texture of the five different brands of piroxicam tablets are presented in Table 2.

Table no: 1 Details of different brands of piroxicam tablets

S.no	Brand Name	Dose	Manufacturer Name	Mfd. date	Exp. date
1.	Mobicam-DT	20mg	Cipla Pvt Ltd,Uttarakhand.	Oct-2021	Sept-2024
2.	Piroxinex-DT	20mg	BRD medilabs,Himachal Pradesh.	Apr-2021	Mar-2024
3.	Doloforce-DT	20mg	Mankind pharma Pvt Ltd,New dehli.	May-2022	Apr-2024
4.	Pirox-DT	20mg	Cipla Pvt Ltd, Uttarakhand.	Aug-2023	Jul-2026
5.	Piroxiking-DT	20mg	Elder pharma , Maharashtra	Feb-2023	May-2026

Table no: 2 Visual characters of piroxicam tablets

S.no	Brand Name	Colour	Shape	Texture
1.	Mobicam-DT	White	Cylindrical	Smooth
2.	Piroxinex-DT	Sunset yellow	Cylindrical	Smooth
3.	Doloforce-DT	Sunset yellow	Circle	Smooth
4.	Pirox-DT	Sunset yellow	Circle	Smooth
5.	Piroxiking-DT	Sunset yellow	Cylindrical	Smooth

Weight variation:

This study examined the weight variation, which is essential for managing the tablet's friability and crushing strength. The assessment focused on the weight variation, which is crucial in regulating the tablet's crushing strength and friability. All five brands' average weight variations fall within the accepted range in terms of weight variation.According to the test results, all five piroxicam brands' samples passed the weight variation uniformity test as required by the IP; not a single brand deviated from the average weight by 5%. When pharmacopeia limits are exceeded, it signifies that the drug content varies accordingly, indicating unacceptably high drugs.

Table no: 3 Weight variation values of piroxicam tablets

S.No	Brand Name	Weight variation (%)
1.	Mobicam-DT	0.0176 ±7.5
2.	Piroxinex-DT	0.0163 ±7.5
3.	Doloforce-DT	0.0202 ±5
4.	Pirox-DT	0.0174 ±7.5
5.	Piroxiking-DT	0.0162 ±7.5

Hardness test and thickness test:

One important in vitro factor that influences disintegration is hardness. Given the correlation between tablet hardness and disintegration, it is imperative that tablet hardness falls within an acceptable range. While tablets with lower hardness are more friable and dissolve faster, those with higher hardness levels often have longer disintegration times. The product's optimal hardness needs to be guaranteed for satisfactory quality. Therefore, appropriate powder resistance and tablet hardness are necessary for high-quality products. All hardness test value satisfies the required standard. The hardness values of brands B and A were highest and lowest, respectively. Brand C had the maximum thickness value in the test, while Brand D received the lowest.

Table no: 4 Hardness and Thickness values of piroxicam tablets

S. No	Brand Name	Hardness in kg/cm2n=10	Thickness (mm)±SD n=10
1.	Mobicam-DT	0.84	0.159
2.	Piroxinex-DT	1.98	0.124
3.	Doloforce-DT	1.69	0.190
4.	Pirox-DT	1.47	0.116
5.	Piroxiking-DT	1.07	0.167

Friability test:

Friability provides details regarding the tablets' mechanical strength. When tablets are subjected to forces from collision and tablet sliding towards one another and other solid substances, which can remove small fragments from tablets' surface, they may be able to withstand abrasion. Usually, a friability tester measures it. All five piroxicam brands have passed the friability test and fulfilled the IP criteria, which states that no brand may lose more than 1% of its starting weight. Table No.5 displays the friability test results. Of the five brands, brand D had the highest friability and brand B the lowest. The outcome might also show how resistant the tablets are to outside pressure during production, shipping, and other processes.

Table no: 5 Friability values of piroxicam tablets

S.no	Brand Name	Friability % n=20
1.	Mobicam-DT	0.656
2.	Piroxinex-DT	0.091
3.	Doloforce-DT	0.343
4.	Pirox-DT	0.851
5.	Piroxiking-DT	0.728

Disintegration test:

Prior to absorption, the medication needs to be in a solution state. The disintegration process which

breaks the tablet down into tiny particles is a crucial first step for the majority of tablets toward solution. Dissolution and bioavailability need to be intimately linked to disintegration. The disintegration time test was used to determine how long a medication would take to break down in the stomach environment. It also displays the medications' profiles of drug release. It was anticipated that the Piroxicam-DT tablet will break down in 13 minutes. This study found that the average disintegration time for dispersible tablets was between 10 and 30 seconds, which is shorter than the typical disintegration duration of 3 minutes.

Table no: 6 Disintegration values of piroxicam tablets

S.no	Brand Name	Disintegration time in seconds
1.	Mobicam-DT	10 seconds
2.	Piroxinex-DT	15 seconds
3.	Doloforce-DT	30 seconds
4.	Pirox-DT	25 seonds
5.	Piroxiking-DT	20 seconds

Dissolution test:

Another factor that was directly connected to the drug's absorption and bioavailability was dissolution. Drugs with poor dissolving profiles won't be absorbed by the body quickly enough to achieve the intended therapeutic effect. The absorption of the tablet is entirely dependent on its disintegration. The rate-limiting stage is dissolution, which comes before absorption. The effectiveness of the tablet is correlated with its dissolving rate. The dissolution rates provide information about %drug release. Brands A and E were respectively the lowest and the highest % of drug release. It is clear from the obtained table no.7 that every brand complies with the specified requirements.

S.no	Brand Name	% of drug content
1.	Mobicam-DT	92.004%
2.	Piroxinex-DT	101.09%
3.	Doloforce-DT	94.04%
4.	Pirox-DT	100.25%
5.	Piroxiking-DT	123.29%

CONCLUSION:

The purpose of this study was to evaluate the physiochemical equivalency and quality of a few piroxicam tablets produced by top pharmaceutical corporations. This study employed a number of quality control metrics for tablets, including weight variation, friability, disintegration time, and dissolving tests. The assessment of the physiochemical parameters showed that every brand of tablet satisfied the quality requirements in terms of weight variation, hardness, thickness, friability, disintegration, and dissolution. It illustrates that these combinations are having the intended NSAID-like effects. According to this investigation, every piroxicam brand examined complied with IP requirements. In general, every brand followed the prescribed guidelines. In order to sufficiently evaluate the therapeutic efficacy, quality, and end-user safety of licensed medications, post-market review is crucial.

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