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# Comparative Pharmacokinetic and Pharmacodynamic Quality Evaluation of Branded and Generic Formulations of Piroxicam

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**Abstract:**

Generic drugs recommendation, provision, and replacement in undeveloped countries has been challenging among physicians, predominantly because of difficulties regarding to quality, safety, and effectiveness Moreover, all these debates are due to variable drug guidelines and rules of every country along with awareness and attitudes of healthcare specialists towards generic drugs. Generic drugs are affordable and less in prize as compared to branded drugs. In the past years generic medicines have been disparaged for being inferior primarily because of poor compliance with good manufacturing practice guiding principle so, the objective of this research is to assess and relate knowledge, attitude, and practice of generic medicines amongst people by their quality assessment and comparison with branded drugs. Present study was carried out by taking branded and generic drugs of Piroxicam and doing all QC testing according to USP. Dissolution, HPLC UV assay, weight variation, friability disintegration tests of both branded and generic brands complies with USP specifications. These generics are cost effective and can be used alternative of branded medicine. Few ratios of doctors have information about generics and there is gap on perception and awareness to generic and brand name drugs. Therefore, extensive knowledge and research is required to fill the gap to the use of generics it will eventually would decrease healthcare expenditure especially in developing countries.

**Key Words:** Generic drugs, weight variation, friability, USP, healthcare

**Introduction:**

A non-steroidal analgesic medicine, piroxicam have its place to the new family oxicam which is a non-selective cyclooxygenase inhibitor. Generally, piroxicam is taken to decrease ache, swelling, and rigorousness triggered by rheumatoid arthritis as well as osteoarthritis. It holds pain-relieving and antipyretic characteristics too [1].

Medications play essential part in keeping health of human body and encouraging healthy life style. Though, security, effectiveness, and quality of the medicine should be determined to deliver acquired pharmacological outcome. Medicines must accomplish regulatory requirements to it insure about its quality. Furthermore, to confirm safety and efficiency of pharmaceuticals, quality is a major criterion. Consequently, in order to get essential quality, all drug manufacturer companies should assure daily QC testing at several stages during and after drug formation process [2]. Drug manufacturer companies must accomplish their regulatory requirements to achieve standards of drug quality [3].



Currently, people are entirely depended on essential drugs for innumerable lifestyle diseases. [4]. Major percentage of the world community meet problems in getting medicines, because of higher rates as expanses are rising 50 times more in the undeveloped countries. Thus, in many countries generic medicines are a substitute to reference around the world [5].

Generics have variable definitions. According to World Health Organization (WHO) Generic medicine is frequently proposed to be substitutable with an innovator product. License from the innovator company is not required for its manufacturing and it is sold after the expiry date of the patent or other exclusive rights [6].

Today, trend of illogical use of medicines is raising because of a diverse factors like knowledge deficiency among the patients, specialists, viable approach adopted by the physicians while

prescribing medicines, pressures on the doctors by the side of patients, money making method of pharmaceuticals as well as lack of execution of strict rules and principles to restrain such actions. Consequently, there is inclusive surge in healthcare budget all over the world. According to World Health Organization approximately 80% of overall health care expenditures are collectively hand to mouth in undeveloped countries. Switch from generics to branded medicines might be another way to decrease drug expenses and reduction in total healthcare budget. US FDA termed generics as a drug that must have the same active ingredient, potency, dosage form, way of administration, quality, efficiency, features and proposed use as the branded medicine. Information about both, approving a switch from brand name medicines to generic counterparts and bioequivalence, can be important and should be addressed in future educational interventions [7].

It is assessed that about $150 billion cost of medicines, globally will be out of patent restrictions from 2010 to 2017, which will support as a platform for drug manufactured companies to develop generic medicine [8]. According to WHO „ Generic and biosimilar medicines promote health equity because they are more affordable and can reach more people Generic drugs offer considerable cost saving potential to healthcare system as compared to their brand name equivalent .Yet, the lack of medical upshots is occasionally taken as the reason for uncertainty in prescribing generic drugs [9]. Generics are replica of branded drugs they just same dosage form, proposed usage, efficiency, pharmacological route, and potency as the innovative. WHO reported that drug accessibility and their cost in public as well as private sectors are main parameters to access disease treatment. Publicly, availability of generics is less than 60% across the WHO areas. Patients are normally forced to buy drugs in the private sector because of less accessibility of drugs in public sectors [10].

| Brand code | Tablets per pack | Price of each pack in PKR | Status |
|---|---|---|---|
| PIRCM01 | 4x10's= 40 tablets | 960.47 | Branded |
| P1RCM02 | 1x10's=10 tablets | 55.21 | Generic |
| P1RCM03 | 2x10's=20tablets | 57.65 | Generic |

A massive amount of healthcare budget of under developing countries goes to buying medicines required in treatment of publicly common diseases. Consequently, access to treatment of disease is confronted by the accessibility of inexpensive drugs. In developing countries medicines are out of reach of about one-third of the people. In the dispute over the use of branded versus generics, customers insights built on their insecurities about the risks involved and, on their perceptions, regarding to the use of generics have been ignored.

Of course brand name medicines put incredible impact in medicines consumption, but it is also a fact that generics that are bioequivalent to their brand, are not only safe but cost-effective [11]. According to WHO cost-savings due to price erosion is an important benefit of utilizing generic medicines. Right choice of drug is most important factor which is considered by doctors, government organizations, consumers and health protection companies to control any disease. Hence price of drug is one of the major challenges particularly in poor countries thus, the use of generics can resolve the issue of cost as generics are 30–95% low in cost than their counterpart innovator brand. Subsequently, in recent past years generics lower the cost of healthcare system [12].

Patients should have knowledge of generics and brand name drugs because it is critical to get generic medicine substitution over branded, to encompass their expenses [13].

The problem regarding to generics is of public health importance particularly in poor countries where availability of critical medicines to common people for ordinarily diseases is frequently hindered by the rising prices of medicines particularly of branded medicines.

The use of generics is not optimal yet because of main fears among doctors and patients about quality as generic drugs are normally thought of lower quality in terms of efficiency and safety as compared to branded medicines. As a result, branded medicines are usually prescribed even when the low prized generic versions are accessible. One reason behind this is lack of confidence of doctors regarding to the quality of generics [14]. This study recommends that authorities invest in publicizing the use of generics and implement public awareness campaigns.

Pharmaceutical sector must fulfill many requirements to control quality of drug. The chief principles for the quality of medicine in dosage form are safe use, strength, effectiveness, stability, suitability of that particular drug along with regulatory compliance as WHO encourage the practice of recommendation generics to minimize healthcare expenditure Moreover, this should be reinforced with acceptable evidence for the replacement of one brand to another [15]. To recognize bioavailability difficulties dissolution testing assists as an indicator. Not only bio pharmaceutically but chemically equivalent drugs must have the same quality, potency, uniformity of content, disintegration test and dissolution profile hence, in vitro quality control of drugs is secure means of inquiry started during manufacturing by in process QC tests and post production through quality control testing of finished products, according to standards of official pharmacopoeias along with different regulatory agencies. Quality control tests assist in evading the misperception about pharmaceutical products [16].

As reported, Pakistan is also comprised in those countries who are the major shipper of medicines. A number of researches were available on physicochemical and pharmaceutical

quality assessment of numerous sold drugs which designated the requirement of drug pharmaceutical equivalence. Additionally, different researchers have worked on the evaluation of pharmaceutical quality and price dissimilarities of different marketed pharmaceuticals [17].

It is very important to compare the current drug generic brands this will helpful in identification of generic brands that are acceptable regarding to their quality and can be used substituent of comparator brand. The present research was conducted to evaluate the quality control parameters to relate the price of piroxicam 20mg tablets of national and international companies including 1 branded (internationally based multinational) 1 nationally available generics and 1 locally available branded generic are collected from different retail pharmacies located at Lahore, Pakistan. Thus, the current research is predominantly targeted at assessment of the dissimilar brands of Piroxicam 20mg tablets with the comparators so, it is struggled to recognize whether there were samples which were deprived of quality. There is a huge price difference between innovator and other generics accessible in the local market. Our current study will be supportive to health-related consultant in prescribing other generics of piroxicam, as the price of other generic drugs are 50% as compared to other brands. Our study has recognized a gap in information and misconceptions about generic drugs among partners of future healthcare workers [18].



## Method and Material

Three different brands of Piroxicam 20mg (1 branded and 2 generics) were collected from local pharmacy of Lahore and coded as PIRCM01, PIRCMO2 and PIRCMO3.All tests were conducted in a quality control laboratory of private pharmaceutical company in Lahore, Pakistan. All tests are performed according to USP Pharmacopeia 2021, Volume III 1168-1168 as follow:

**1. Average weight:**

20 tablets of PIRCM01were taken at random and the combined weight of all tablets were noted. Analytical balance JF model JF2104N is used for this purpose. Calculated the average weight using the following formula:

Average weight (mg) = Total weight of 20 tablets (mg) / 20

**NOTE:** Calculate and report the average weight in milligrams rounded to one decimal place.

Average weight of PIRCM02 and PIRCM03 were calculated in the same way.

**2. Weight Variation:**

20 tablets of PIRCM01 were taken on watch glass. First tared the weight of watch glass and put the tablets on it. Weight of 20 tablets were noted and tared weight again. Tablets were weighed one by one, by picking one tablet from watch glass and weight were noted.

Weight variation of PIRCM02 and PIRCM03 were calculated in the same way.

**NOTE:** Check all the tablet weights. Not more than 2 out of 20 tablets deviate from ± 5.0 % and none from ± 10 % of average weight.



**3. Hardness:**

Hardness of tablets of PIRCM01 were determined in Kg using a calibrated hardness tester model GHT-1 and calculated their average using the following formula.

Average Hardness = Sum of Hardness of 10 tablets / 10

**NOTE:** Calculate and report the average hardness of tablets in Kg rounded to one decimal place.

Hardness of PIRCM02 and PIRCM03 were calculated in the same way.

**4. Friability:**

Sample of whole tablet of PIRCM01 were taken equivalent to 6.5 g. Tablets were de-dusted prior to testing and accurately weighed the tablets. Weight was noted as $W_1$. Opened one of the drum of friability tester model FT-L and placed the tablet in the drum. After the completion of

desired revolutions, removed the tablets and also removed loose dust from the tablets. Again, tablets were weighed and noted as $W_2$, the % friability was calculated by the formula

$$\% \text{ Friability} = (W_1 - W_2) \times 100 / W_1$$

**NOTE:** Report the friability of tablets in percentage rounded to one decimal place.

Friability of PIRCM02 and PIRCM03 were calculated in the same way.

**5. Disintegration Time:**

**Test conditions:**

| **Apparatus:** | **Six basket assembly** |
|---|---|
| Medium: | Distilled water |
| Volume: | 750 – 800 mL |
| Temperature: | 37°C ± 2°C |
| Time: | 15 minutes |



**Procedure:**

After temperature had been equilibrated, introduced one tablet of PIRCM01 into each tube and disk of D.T. apparatus model 121-P. Suspended the assembly in the beaker containing the medium and operated the instrument for the specified time and see the tablets. Time was noted when all the tablets disintegrated completely and no particle of tablets was present on the sieve.

**NOTE:** Report the disintegration time in minutes rounded to whole number.

Friability of PIRCM02 and PIRCM03 were calculated in the same way.

**6. Dissolution:**

| | |
|---|---|
| Apparatus: | USP apparatus II (Paddle) model Sigma-14LP |
| Revolution: | 100 RPM |
| Medium: | 0.1N Hydrochloric Acid, 900ml |
| Temperature: | 37 $^0$C ± 0.5 $^0$C |
| Time: | 45 minutes |
| UV: | 242 nm |

**Sample Preparation:**

900ml of 0.1N HCl as dissolution medium were added in each of six vessels of dissolution apparatus model Sigma-14L and equilibrated at 37ºC±0.5ºC. One tablet of brand PIRCM01 is placed in each vessel and rotated paddle immediately at 100RPM for 45 minutes.

After half hour and 15 minutes about 10 mL sample were withdrawn, filtered and then absorbance was measured at $\lambda_{max}$ 242 nm.



**Standard Preparation:**

Accurately weighed 20mg Piroxicam WS in 100mL volumetric flask, about 60mL to 80mL of 0.1N HCl were added, mixed with the aid of ultrasound, cooled and make up the volume with 0.1N HCl. Diluted 5 mL of the filtrate to 50mL with 0.1N HCl

**Observations and Calculations:**

Calculated the Piroxicam %, using the following formula

$$\frac{A \times W_1 \times 5 \times 100 \times 50 \times W_3 \times P}{B \times 100 \times 50 \times W_2 \times 5 \times 20}$$

Where,

| | |
|---|---|
| A | Absorbance of sample |
| B | Absorbance of standard |
| W1 | Weight of working standard |
| W2 | Weight of sample |
| W3 | Average weight of 20 tablets |
| P | Potency of working standard on as is basis |

Dissolution of PIRCM02 and PIRCM03 were performed in the same way.

**7. Assay of Piroxicam:**

**Liquid Chromatography:**

| | |
|---|---|
| Column specification | Stainless steel column (4.6 mm × 25 cm, 5 µm Packing L1) |
| Temperature of column: | Ambient |
| Flow rate: | 2.0 mL per minute |
| UV detector: | 242nm |
| Injection volume: | 20 µL |

**Mobile Phase:**

Methanol: Buffer (60: 40)

**Buffer:**

Buffer solution was prepared by addition of solution encompassing about 5.35 g of disodium hydrogen orthophosphate in 100 mL of distilled water it was added to a solution containing 7.72 mL of citric acid in 400 ml of water, diluted to 1000 mL.

**Sample Preparation:**

20 tablets of PIRCM01 were triturated and the powder were accurately weighed equivalent to 10 mg of piroxicam to 150mL of 0.01M methanolic HCl, mixed on ultrasound bath for half hour, then cooled, diluted to 200mL by solvent used. Filtered sample through glass fiber paper. Diluted 5mL of the filtrate to 50mL volumetric flask with same solvent.

Samples of PIRCM02 and PIRCM03 were prepared in the same way.

**Standard Preparation:**

Accurately weighed 10mg Piroxicam WS in 200mL volumetric flask, about 60mL to 80mL of 0.01M Methanolic HCl were added, mixed with the aid of ultrasound, cooled and make up the volume with 0.01M Methanolic HCl. Diluted 5 mL of the filtrate to 50mL with same solvent. 20µl of blank, standard (two times) and sample (five times) were injected in HPLC model water Alliance and chromatogram was recorded



Observations and Calculations:

Calculated the Piroxicam %, using the following formula

$$\frac{A \times W_1 \times 5 \times 200 \times 50 \times W_3 \times P}{B \times 200 \times 50 \times W_2 \times 5 \times 20}$$

Where,

| | |
|---|---|
| A | Peak area of sample |
| B | Peak area of standard |
| $W_1$ | Weight of working standard |
| $W_2$ | Weight of sample |
| $W_3$ | Average weight of 20 tablets |
| P | Potency of working standard on as is basis |

Limit: 90.0 - 110 % of label claim

Chromatographic Assay of PIRCM02 and PIRCM03 were performed in the same way.

**8. Assay of Piroxicam by UV:**

**Sample Preparation:**

20 Tablets of PIRCM01 were taken and triturated, powder equivalent to 20mg Piroxicam were taken in 60ml 0.1M NaOH, dissolved by mixing for 10-15 minutes with gentle heat, added more 0.1M NaOH to make volume 100ml, filtered, 5ml of sample was taken and diluted to 50ml with 0.1M NaOH and absorbance was measured at about 251nm using 0.1M NaOH as a blank.

Samples of PIRCM02 and PIRCM03 were prepared in the same way.

**Standard Preparation:**

20mg Piroxicam were taken in 60ml 0.1M NaOH, dissolved by mixing for 5-7 minutes with gentle heat, 0.1M NaOH were added to make volume 100ml, 5ml were taken and diluted to 50ml with 0.1M NaOH and absorbance was measured at about 251nm using 0.1M NaOH as a blank.



Standard and sample were run on UV model ShimadzuUV-1900i and absorbance were noted in nm. Calculated the Piroxicam %, using the following formula

$$\frac{A \times W_1 \times 5 \times 100 \times 50 \times W_3 \times P}{B \times 100 \times 50 \times W_2 \times 5 \times 20}$$

| | |
|---|---|
| A | Absorbance of sample |
| B | Absorbance of standard |
| $W_1$ | Weight of working standard |
| $W_2$ | Weight of sample |
| $W_3$ | Average weight of 20 tablets |
| P | Potency of working standard on as is basis |

Limit: 90.0 - 110 % of label claim

Samples of PIRCM02 and PIRCM03 were run in the same way.

| | | |
|---|---|---|
| 1 | **Hardness** | NLT 5 Kg |
| 2 | **Friability** | NMT 1.0% |
| 3 | **Disintegration Time** | NMT 15 minutes |
| 4 | **Dissolution** | Q = 70%<br>(Should comply the acceptance criteria of dissolution) |
| 5 | **Assay**<br>(Piroxicam) | 90- 110% |

**Result and Discussion:**

To approve quality of conservative tablets, weight variation test, friability, disintegration test, dissolution rated, assay of drug, content uniformity test is compulsory to accomplish. Friability test is used to estimate strength of tablet. Its allowed limit is maximum 1%. Friability test is frequently used to check probable wear and tear loss in the tablet while transporting from one place to another and this is closely associated to hardness of tablet. Purpose of weight variation test to maintain uniform weight while process of manufacturing. It is used is to confirm the uniformity of each tablet batch thus uniformity of content in all tablet batches.

Disintegration is criteria used to estimate time taken by tablet to disintegrate in the tiny units moreover, in the body this is primary step before dissolution of drug. The disintegration test condition must be same as in the body to fulfill in-vivo and in-vitro co-relation.

The most important test dissolution, used to evaluate the pattern of release of drug. Dissolution also give information of bioavailability of tablet hence; dissolution gives the data about the safety and effectiveness of drug in dosage form. Assay of drug is compulsory to approve that in a dosage form the labelled amount of drug is present. Our weight variation of given results in table 1.1 revealed that all the 20 arbitrarily selected tablets of mentioned three brands are within the limit of weight variation test as less than 5 %. PIRCM01, PIRCM02 and PIRCM03 are within the upper and lower control limit defined by USP. It indicated that all tablets of mentioned brands available in Lahore Pakistan passed this test.

Hardness testing data given in table 1.2 for all brands of Piroxicam tablet showed that each brand sample comply the defined harness limit that was NOT LESS THAN 5 kg. The multinational tablet brand sample PIRCM01 is hardest among all samples with a hardness of 19.7kg. PIRCMO2 is less hard as compared to other two sample brands.

Friability data given in table 1.3 showed that multinational tablet brand sample PIRCM01 showed minimum value for friability as compared to PIRCM02 and PIRCM03 which are local generics. The given data of table 1.3 confirmed that both branded and generics samples of piroxicam tablets are within the pharmacopoeia range as not more than 1% indicated that all these selected piroxicam tablets brands, available at Lahore pharmacies have good strength and they can bear the shocks throughout the process of transportation.

The test data of disintegration displayed in tablet 1.4 showed that all three different brands of piroxicam tablet disintegrate not exceeding 6 minutes. Brand code PIRCM01 has disintegration time of 2 minutes whereas P1RCM02 and PIRCM03 both showed disintegration time of 3 minutes. This time is according to USP mentioned time limit (15 minute for core tablet). It showed that all three piroxicam brands passed the test limits of USP.

Qualitative drug assay of UV (table 1.5) and HPLC (table 1.9, 1.10) that all three piroxicam tablets brands showed that quantity of piroxicam drug present in mentioned brands of formulated tablets is about 100 %. It indicated that drug is available according to mentioned value in stable dosage form. Brand code PIRCM03 showed maximum drug release percentage (100.46 %) followed by PIRCM01 (99.95%) and PIRCM02 (99.83%). HPLC assay of brand code PIRCM02 and PIRCM03 both local brands showed excellent drug release percentage value 101.83% and 101.68% respectively. The multinational brand relieved ideal results of 100.74%.

Dissolution data of all tested brands of piroxicam tablets given in tables 1.6-1.7 showed that all six tablets of each brand comply the USP defined limit of dissolution. Not a single tablet of

all brand codes PIRCM01, PIRCM02 and PIRCM03 was below the USP dissolution limit Q+5=75%.

**Instruments used for QC testing:**

| Brand code | Average weight of 20 tablets (mg) | Upper control limit(mg) | Lower control limit(mg) | Result |
|---|---|---|---|---|
| PIRCM01 | 557.7 | 613.47 | 501.93 | Complies |
| P1RCM02 | 136.7 | 150.37 | 123.03 | Complies |
| P1RCM03 | 320.5 | 352.55 | 288.45 | Complies |

**Table 1.1 Weight variation (mg) of different brands of Piroxicam tablet**

| Brand code | Average Hardness of 10 tablets (kg) | Control limit | Result |
|---|---|---|---|
| PIRCM01 | 19.7 | NLT 5kg | Complies |
| P1RCM02 | 7.67 | NLT 5kg | Complies |
| P1RCM03 | 11.0 | NLT 5kg | Complies |



**Table 1.2 Average Hardness (kg) of different brands of Piroxicam tablet**

| Brand code | Friability (%) | Limit (w/w) | Result |
|---|---|---|---|
| PIRCM01 | 0.068 | NMT 1 % | Complies |
| P1RCM02 | 0.562 | NMT 1 % | Complies |
| P1RCM03 | 0.155 | NMT 1 % | Complies |

**Table 1.3 Friability (%) of different brands of Piroxicam tablet**

| Brand code | Disintegration Time (D.T) (minutes) | USP Limit | Result |
|---|---|---|---|
| PIRCM01 | 2 minutes | NMT 15 minutes | Complies |
| P1RCM02 | 3 minutes | NMT 15 minutes | Complies |
| P1RCM03 | 3 minutes | NMT 15 minutes | Complies |

**Table 1.4 Disintegration time (minutes) of different brands of Piroxicam tablet**

| Brand code | Absorbance of sample (nm) | Absorbance of standard (nm) | Percentage of drug released (%) | USP limit (%) | Result |
|---|---|---|---|---|---|
| PIRCM01 | 0.872 | 0.763 | 99.95 | 90-110 | Complies |
| P1RCM02 | 0.748 | 0.763 | 99.83 | 90-110 | Complies |
| P1RCM03 | 0.709 | 0.763 | 100.46 | 90-110 | Complies |

**Table 1.5 UV Assay (%) of different brands of Piroxicam tablet**

| Brand code | Absorbance of sample (nm) | Absorbance of standard (nm) | Drug released (Q) (%) | USP limit (%) | Result |
|---|---|---|---|---|---|
| PIRCM01 T1 | 0.778 | 0.683 | 102.57% | Q+5=75% | Complies |
| PIRCM01 T2 | 0.774 | 0.683 | 99.98% | Q+5=75% | Complies |
| PIRCM01 T3 | 0.774 | 0.683 | 101.09% | Q+5=75% | Complies |
| PIRCM01 T4 | 0.780 | 0.683 | 102.07% | Q+5=75% | Complies |
| PIRCM01 T5 | 0.765 | 0.683 | 99.90% | Q+5=75% | Complies |
| PIRCM01 T6 | 0.771 | 0.683 | 101.96% | Q+5=75% | Complies |

**Table 1.6 Dissolution (Q) of brand PIRCM01 of Piroxicam tablet**

| Brand code | Absorbance of sample (nm) | Absorbance of standard (nm) | Drug released (Q) (%) | USP limit (%) | Result |
|---|---|---|---|---|---|
| PIRCM02 T1 | 0.744 | 0.683 | 103.21% | Q+5=75% | Complies |
| PIRCM02 T2 | 0.760 | 0.683 | 99.10% | Q+5=75% | Complies |
| PIRCM02 T3 | 0.738 | 0.683 | 100.77% | Q+5=75% | Complies |
| PIRCM02 T4 | 0.736 | 0.683 | 95.06% | Q+5=75% | Complies |
| PIRCM02 T5 | 0.729 | 0.683 | 93.20% | Q+5=75% | Complies |
| PIRCM02 T6 | 0.716 | 0.683 | 92.14% | Q+5=75% | Complies |

**Table 1.7 Dissolution (Q) of brand PIRCM02 of Piroxicam tablet**

| Brand code | Absorbance of sample (nm) | Absorbance of standard (nm) | Drug released(Q) (%) | USP limit (%) | Result |
|---|---|---|---|---|---|
| PIRCM03 T1 | 0.737 | 0.683 | 102.87% | Q+5=75% | Complies |
| PIRCM03 T2 | 0.731 | 0.683 | 96.89% | Q+5=75% | Complies |
| PIRCM03 T3 | 0.724 | 0.683 | 100.66% | Q+5=75% | Complies |
| PIRCM03 T4 | 0.705 | 0.683 | 97.53% | Q+5=75% | Complies |
| PIRCM03 T5 | 0.698 | 0.683 | 85.86% | Q+5=75% | Complies |
| PIRCM03 T6 | 0.741 | 0.683 | 99.97% | Q+5=75% | Complies |

**Table 1.8 Dissolution (Q) of brand PIRCM03 of Piroxicam tablet**

| Brand code | Peak area of sample | Peak area of standard | Average | Assay | USP limit | Result |
|---|---|---|---|---|---|---|
| PIRCM01 | 1292872.47 | 11588694.13 | | 100.74% | 90-110% | Complies |
| | 13013541.85 | 11729541.88 | 11659118 | | | |
| | 13114706.46 | | | | | |
| | 12941663.98 | | | | | |
| | 13011511.36 | | 13002859 | | | |



**Table 1.9 HPLC assay of brand PIRCM01 of Piroxicam tablet**

| Brand code | Peak area of sample | Peak area of standard | Average | Assay | USP limit | Result |
|---|---|---|---|---|---|---|
| PIRCM02 | 1292872.47 | 14226988.21 | | 101.83% | 90-110% | Complies |
| | 13013541.85 | 14259266.84 | 1424317 | | | |
| | 13114706.46 | | | | | |
| | 12941663.98 | | | | | |
| | 13011511.36 | | 13002859 | | | |

**Table 1.10 HPLC assay of brand PIRCM02 of Piroxicam tablet**

| Brand code | Peak area of sample | Peak area of standard | Average | Assay | USP limit | Result |
|---|---|---|---|---|---|---|
| PIRCM02 | 1292872.47 | 12961360.45 | | 101.68% | 90-110% | Complies |
| | 13013541.85 | 12964909.55 | 12963135 | | | |
| | 13114706.46 | | | | | |
| | 12941663.98 | | | | | |
| | 13011511.36 | | 13002859 | | | |

**Table 1.11 HPLC assay of brand PIRCM03 of Piroxicam tablet**

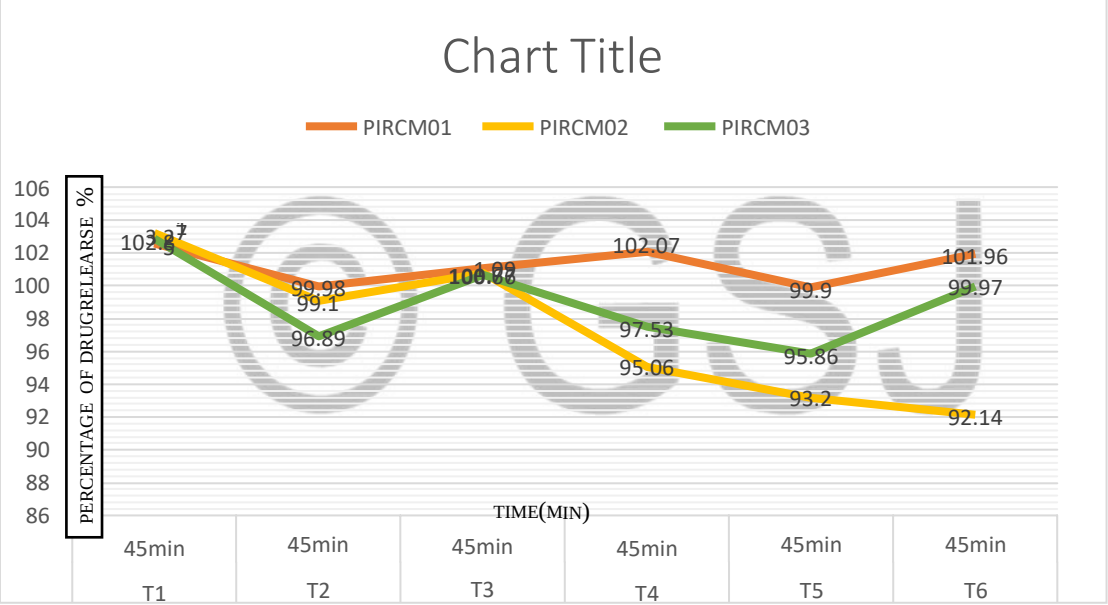


**Figure 1.2 Dissolution of Different piroxicam brands**

## Conclusion

This study showed an effort to assess the quality along with the physicochemical equivalence of branded and generic brands of piroxicam tablets. The quality assessment presented that all different three brands of tablets met the quality standards of USP regarding to test of weight variation, disintegration, hardness, friability test, dissolution and drug assay. Even though some physicians had good information and attitude related to generics but this is not used while prescribing a medicine which is showing the big gap between knowledge, attitude and practice. Main concern is awareness which should be enhanced through consistent trainings and workshops as repeated education related to drugs. Predominantly, physicians should instruct early right from their undergraduate career regarding to generic medicines. It supports to enhance confidence in them, which eventually result of rise in generics prescription. More research on generics should be done and data should be broadly published that definitely would increase knowledge regarding to use of generic medicines.
Our comparable results of branded and generics could help in endorsing educational interventions intended in increasing patient and doctor confidence in the capability of generics drugs to accomplish chronic diseases.

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