Journal of Pharmaceutical Research International

32(32): 82-87, 2020; Article no.JPRI.61161
ISSN: 2456-9119
(Past name: British Journal of Pharmaceutical Research, Past ISSN: 2231-2919, NLM ID: 101631759)

Evaluation of Physicochemical Parameters of Piroxicam 20 mg Tablets Commercially Available in District Larkana, Sindh

Waqar Ahmed[1], Muhammad Ali Ghoto[2], Ubed-ur-Rehman Mughal[1], Abdullah Dayo[1], Mudassar Iqbal Arain[2], Arslan Ahmer[3*], Rao Irfan[3], Bilawal Shaikh[3], Maryam Qazi[4] and Komal Zaman Khan[5]

[1]Department of Pharmaceutics, Faculty of Pharmacy, University of Sindh, Jamshoro, Sindh, Pakistan.
[2]Department of Pharmacy Practice, Faculty of Pharmacy, University of Sindh, Jamshoro, Sindh, Pakistan.
[3]Institute of Pharmaceutical Sciences, People's University of Medical and Health Sciences for Women (PUMHSW), Nawabshah, Sindh, Pakistan.
[4]Institute of Pharmacy, Shaheed Mohtarma Benazir Bhutto Medical University (SMBBMU) Larkana, Sindh, Pakistan.
[5]College of Pharmacy, Liaquat University of Medical and Health Sciences (LUMHS), Jamshoro, Sindh, Pakistan.

Authors' contributions

This work was carried out in collaboration among all authors. Author WA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors AA and RI managed the analyses of the study. Authors BS and MQ managed the literature searches. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2020/v32i3230936
Editor(s):
(1) Dr. Rahul S. Khupse, University of Findlay, USA.
Reviewers:
(1) Rachana Bhimanwar, Savitribai Phule Pune University, India.
(2) G. K. Chetan Kumar, Karnataka Veterinary, Animal and Fisheries Sciences University, BIDAR, India.
(3) N. S. Sampath Kumar, Vignan's Foundation for Science, Technology & Research, India.
Complete Peer review History: http://www.sdiarticle4.com/review-history/61161

Original Research Article

Received 19 July 2020
Accepted 23 September 2020
Published 03 December 2020

ABSTRACT

The objective of this study is to evaluate the physicochemical parameters of Piroxicam 20 mg Tablet brands. A comparative qualitative research study was conducted for a period of six months. A total of five different brands of active Piroxicam tablets were selected. All samples were

**Corresponding author: E-mail: arslan.ahmer@gmail.com;*

purchased from various local markets of Larkana Sindh. These collected samples were coded as PIX01, PIX02, PIX03, PIX04 and PIX05 for minimalism. Specific physicochemical quality control lab tests included Aesthetic test, Diameter and Thickness test, Weight variation, Mechanical strength and Friability test were performed on each sample according to standards and results were compared. Packing of all samples was observed according to GMP guidelines. Data was analyzed by using statistical software SPSS 24.00. Most of the brands were within official limits of United State Pharmacopeia (USP) except brand PIX05 showing variation in hardness test, whereas two brands PIX03 and PIX05 fail in friability test as well as powder material seen inside of blisters in aesthetic test. Dissolution test for each brand of Piroxicam was performed in which PIX02, 04 and 05 failed. It was concluded that from this study after in vitro physical evaluation of various brands of Piroxicam tablets, most of the brands are being manufactured under compliance of GMP guidelines as well as specifications described under USP. Traces of powder material inside of blister in aesthetic test and unsatisfactory result in friability and hardness test in same brand indicating the deviation of GMP guidelines and USP specification which may cause the out of specification result in chemical test.

Keywords: Piroxicam; NSAIDS; diameter; analgesic; friability.

1. INTRODUCTION

Pain is worrying sensation, which is caused by forceful diminishing of spurs or inducement, another specific definition for the pain which is being described by the international association for the study of pain [1], A hostile corporeal and sensitive familiarities associated with actual and potential damage of such type of tissues or may be defined as diminishing of such type of tissues, where as in medical science It has various outline for its definition or description [2]. In medical field pain is a complex phenomenon, which is appeared with variety of symptoms as it appeared as challenge which need to be solved [3]. Whenever we are discussing the pain management everybody want to get rid of from unpleasant sensation and everybody want to recover the damaged tissue and avoiding to have same exposure in future some time pain is recovered by removing the harmful stimuli and body is recovered whereas some time pain appears within body without identifying any noxious stimulus or without any damaging of tissues – pain is only reason for the consultation of physician in many developing counties [4], as whenever patients feels unpleasant sensation it alter the normal physiology of the patient and medically patients want to recover from distressing feelings. Simple pain killer medicines are used up to 70% besides this various factor are also involved to reduce the intensity of pain [5]. Such as factors associated with psychology of the person [4] e.g:- Social support excitement, hypnotic recommendation these factors are also used frequently along with medicine to reduce the pain and unwanted sensation either acute or chronic [5]. In rare case it is also observed that physician suggest for euthanasia when all others reasons for pain management become fruitless. When person is suffering from severe illness with rich intensity of pain than he may trying to withdraw from his life and more for euthanasia [6].

Pain is not a permanent disorder of dysfunction of the body, it can be rectified till the damaged tissue are being removed or till when dysfunction of any system is resolved and body function normally. Sometime pain remains within body until the pathological factors causing pain are removed from the body [7]. Such as; Rheumatoid arthritis, peripheral neuropathy, tumor or idiopathic pain, these type of pain remains within the body for long duration of time up to several years. Pain is said to be chronic, if it remains for the long duration and if the pain remains for short duration is known as acute [7,8]. The major difference between acute and chronic is only duration of onset on other hand both types of pain have same intensity.

The objective of this study is to evaluate the physicochemical parameters of Piroxicam 20 mg Tablet brands.

2. MATERIALS AND METHODS

A comparative randomized study was conducted on various brands of Piroxicam purchased from local market of Larkana city. Various physicochemical tests were conducted on all brands and results were compared with standards of USP. Each test was performed with specified apparatus and glass wares as per recommendation. Physicochemical tests were

included aesthetics test, weight variation test, thickness test, Hardness test, friability test. For dissolution, disintegration and chemical assay, the sample was prepared by dissolving it with various organic solvents in accordance with the need of apparatus used for each test. Total 05 different brands of Piroxicam were taken in order to perform physicochemical tests city and each brand was labeled with the names of PIX01, PIX02, PIX03, PIX04 and PIX05.

3. RESULTS

A comparative randomized study was conducted on five different brands of Piroxicam purchased from local market of Larkana. Physicochemical tests including Weight variation test, Thickness test, Hardness test, Friability, Dissolution, Disintegration & Chemical assay were performed and the results were summarized in tabular form. Before these entire physical and chemical evaluation tests, Aesthetic test was performed to evaluate each tablet with organs of sense such as Eyes and the obtained results were compared with the standards available in USP. Specified and recommended apparatus and glass wares were used accordingly.

Results for weight variation of the various brands of Piroxicam are mentioned in Table 1.

Thickness for the various brands of Piroxicam are mentioned in Table 2.

Diameter of each brands can were calculated and the results for all various brands of Piroxicam are mentioned in Table 3.

The aver all results of Friability test of all various brands of Piroxicam are mentioned in Table 4.

The results for the various brands of Piroxicam with reference to their disintegration are mentioned in Table 5.

Chemical assay was also performed on all the various brands of Piroxicam and the results of chemical assay for all brands of Piroxicam as mentioned Table 6.

Table 1. Results of weight variation of all various brands of Piroxicam (20 mg) brands with limits

Name of brands	Average weight of 20 tablets (gm)	Allowed limit ± 10%	Upper control limit	Lower control limit	Results
PIX01	11.08	0.0554	0.6094	0.4986	Pass
PIX02	3.36	0.0168	0.184	0.1512	Pass
PIX03	10.87	0.054	0.594	0.486	Pass
PIX04	11.20	0.056	0.616	0.504	Pass
PIX05	6.95	0.034	0.374	0.306	Pass

Table 2. Results of all various brands of Piroxicam brands for average thickness (mm) with limits

Name of Samples	Average thickness (mm) of 10 tablets	Allowed limit (mm) ±5% & ±3%	Upper limit (mm)	Lower limit (mm)	Results
PIX01	5.469	0.273	5.74	5.196	Pass
PIX02	2.748	0.137	2.88	2.61	Pass
PIX03	5.285	0.264	5.549	5.021	Pass
PIX04	4.90	0.245	5.14	4.65	Pass
PIX05	4.00	0.20	4.2	3.8	Pass

Table 3. Results of all various brands of Piroxicam brands for diameter (mm) with limits

Name of samples	Average diameter (mm) of 10 tablets	Allowed limit (mm) ±5% & ±3%	Upper limit (mm)	Lower limit (mm)	Results
PIX01	17.45	0.872	18.32	16.57	Pass
PIX02	8.519	0.425	8.944	8.094	Pass
PIX03	17.142	0.857	17.99	16.28	Pass
PIX04	17.312	0.865	18.177	16.44	Pass
PIX05	10.087	0.504	10.591	9.583	Pass

Table 4. Results of friability test on various brands of piroxicam tablet

Name of samples	Results	Allowed limit	Status
PIX01	0%	1%	Pass
PIX02	0%	1%	Pass
PIX03	11%	1%	Fail
PIX04	0.1%	1%	Pass
PIX05	6%	1%	Fail

Table 5. Disintegration results for all brands of Piroxicam

Name of brands	Average disintegration time	Allowed limit in USP
PIX01	Less than 2 min	5 minutes
PIX02	Less than 2 min	5 minutes
PIX03	4 minutes	5 minutes
PIX04	3 minutes	5 minutes
PIX05	2 minutes	5 minutes

Table 6. Chemical assay for Piroxicam standard and sample

Peaks areas		Mean	% Assay
Peak area of Standard 01	832786	849029	
Peak area of Standard 02	865273		
Peak area of Sample 1 a	830361	826258	97.32
Peak area of Sample 1 b	822155		
Peak area of Sample 2 a	836570	848097	99.89
Peak area of Sample 2 b	859624		

Table 7. Dissolution for PIX01, PIX02, PIX03, PIX04 and PIX05

PIX01	Abs. of Sample	Abs. of Std.	% drug dissolved	Remarks
Sample 01	0.6925	0.7795	88.84	Pass
Sample 02	0.6885	0.7795	88.33	Pass
Sample 03	0.685	0.7795	88.88	Pass
Sample 04	0.6905	0.7795	88.58	Pass
Sample 05	0.68	0.7795	87.24	Pass
Sample 06	0.662	0.7795	84.93	Pass
MEAN			**87.63**	**Pass**
PIX02				
Sample 01	0.027	0.7795	3.46	Fail
Sample 02	0.026	0.7795	3.34	Fail
Sample 03	0.038	0.7795	4.87	Fail
Sample 04	0.025	0.7795	3.21	Fail
Sample 05	0.031	0.7795	3.98	Fail
Sample 06	0.034	0.7795	4.36	Fail
MEAN			**3.87**	**Fail**
PIX03				
Sample 01	0.6235	0.7795	79.99	Pass
Sample 02	0.6035	0.7795	77.42	Pass
Sample 03	0.609	0.7795	78.13	Pass
Sample 04	0.631	0.7795	80.95	Pass
Sample 05	0.613	0.7795	78.64	Pass
Sample 06	0.6125	0.7795	78.58	Pass
MEAN			**78.95**	**Pass**
PIX04				

Sample 01	0.5265	0.7795	67.54	Fail
Sample 02	0.499	0.7795	64.02	Fail
Sample 03	0.519	0.7795	66.58	Fail
Sample 04	0.5155	0.7795	66.13	Fail
Sample 05	0.537	0.7795	68.89	Fail
Sample 06	0.5725	0.7795	73.44	Fail
MEAN			**67.77**	**Fail**
PIX05				
Sample 01	0.3135	0.7795	40.22	Fail
Sample 02	0.321	0.7795	41.18	Fail
Sample 03	0.3645	0.7795	46.76	Fail
Sample 04	0.324	0.7795	41.57	Fail
Sample 05	0.3425	0.7795	43.94	Fail
Sample 06	0.3645	0.7795	46.76	Fail
MEAN			43.40	Fail

Dissolution test for each brand of Piroxicam was performed by taking NLT 75% dissolved in 45 minutes (USP) as standard acceptance criteria. PIX02, 04 and 05 failed as described in Table 07.

4. DISCUSSION

The current study was finalized with a purpose to evaluate the variation among numerous brands of Piroxicam and also assess that either brand was containing counterfeit drugs and which one among all was considered as cost effectiveness brand at the local pharmaceutical market of larkana district Pakistan. According to research carried out by Mitali Kakran et al 2012 said that number of counterfeit drugs were freely available in the market with not more than 40% of bioavailability [9] and according to report published by US Food and Drug Administration 1985 that 10-15% of total pharmaceutical products comprises of fake medicines either placebo or very less quantity of active ingredients or the active ingredients which was used in that type of medicines was not authenticate or very low quality [10]. Vijay kumar et al 2010 concluded a research upon the variation between generic and brands tablets of Piroxicam locally accessible in the markets of India, to evaluate the quality as well as cost of medicines to know that whether these medicines were prepared according to official limits of Pharmacopeia [11]. Pavani Vengala et al 2013 conducted a research study of 05 commercial brands of Piroxicam with a purpose of evaluating the physical inspection, active ingredients release pattern of drug on various brands of Piroxicam randomly selected. On these brands of tablets, physical investigations was applied to evaluate the shape, size, weight and color of the tablet. Along with these test all the brands of tablets were tested for friability, purity, assay and disintegration according to official procedures mentioned in pharmacopeia [12]. The current study also described the effective differences that was observed among tested brands of Piroxicam including weight and drug content test.

5. CONCLUSION

All the tested brands of Piroxicam were in accordance with official requirement available in USP Pharmacopeia. Aesthetic test, Weight variation, Hardness, Diameter and Thickness results of all the brands were within official limitation given in USP. Only two brands did not satisfy the test of Friability. Dissolution test for each brand of Piroxicam was performed in which PIX02, 04 and 05 failed. Dissolution criteria were also satisfy the official requirement and within given limitation available in USP. All the brands also cleared the assay test with highest drug content of 105% and lowest drug content of 95%. It is concluded from the research that no any brand was counterfeit or substandard so these can be considered as interchangeable and therapeutic equivalent.

CONSENT

It is not applicable.

ETHICAL APPROVAL

The SMBBMU Larkana Ethics Committee approval has been collected and preserved by the author.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Charoo NA, Shamsher AA, Zidan AS, Rahman Z. Quality by design approach for formulation development: A case study of dispersible tablets. Int J Pharm. 2012; 423(2):167-78.
2. Kalyankar P, Panzade P, Lahoti S. Formulation design and optimization of orodispersible tablets of quetiapine fumarate by sublimation method. Indian J Pharm Sci. 2015;77(3):267-73.
3. Saleh MA, Mohammed SA, Abdullah EC, Hashim LA. Enhancement the Dissolution Rate and Solubility of Poorly Soluble Drugs. Review in Advanced Materials Research. 2013;701:234-38.
4. Saboji J, Manvi V, Gadad P, Patel D. Formulation and evaluation of ketoconazole microsponge gel by quasi emulsion solvent diffusion. J Cell and Tissue Res. 2011;11:2691-96.
5. Karthika R, Elango K, Kumar K, Rahul K. Formulation and evaluation of lorn oxicam micro sponge tablets for the treatment of arthritis, Int J Pharm Innovations. 2013;3: 2940. .
6. Jain SK, Cherian AK, Rana AC. Self-assembled carbohydrate-stablized ceramic nanoparticles for the parenteral delivery of insulin. Drug Dev Ind Pharm. 2000; 26(4):459-63.
7. Mohan KV, Veena NM, Manjula BP. Formulation and evaluation of microsponges for topical drug delivery of mupirocin. Int J Pharm Technol Res. 2013;5:1435-40.
8. Qiao N, Li M, Schlindwein W, Malek N, Davies A, Trappitt G. Pharmaceutical cocrystals: An overview. Int J Pharm. 2011;419(1-2):1-11.
9. Mitali K, Li L, Rainer HM. Overcoming the Challenge of poor Drug Solubility. Pharmaceutical Engineering. 2012;32(4): 82-89.
10. US Food and Drug Administration. 'COSTAR7, coding symbols for the saurus of adverse reaction tenns. 2nd ed. Maryland: Food and Drug Administration; 1985.
11. Vijay KN, Venkateswarlu V, Raviraj P. Research Journal of Pharmaceutical, Biological and Chemical Sciences. Development of oral tablet dosage form incorporating drug nanoparticles. RJPBCS. 2010;1(4):952.
12. Pavani V, Swetha D, Chavali VSS. Lactose coated ceramic nanoparticles for oral drug delivery. Journal of Pharmacy Research. 2013;7:540-45.

Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sdiarticle4.com/review-history/61161