

Quality Assessment and Dissolution Profile Comparison Studies on Naproxen Tablets Available in Karachi

Fatima Qamar*, Samina Alam, Safila Naveed, Huma Ali

Faculty of Pharmacy, Jinnah University for Women, Karachi, Pakistan

ABSTRACT

Keywords: Physicochemical parameters, naproxen, model independent, model dependent method.

Author's Contribution

All the authors contributed significantly to the research that resulted in the submitted manuscript.

Article info.

Received: October 11, 2016

Accepted: December 12, 2016

Funding Source: Nil

Conflict of Interest: Nil

Cite this article: Qamar F, Alam S, Naveed S, Ali H. Quality Assessment and Dissolution Profile Comparison Studies on Naproxen Tablets Available in Karachi. *RADS J. Pharm. Pharm. Sci.* 2017;5(2):32-35.

*Address of Correspondence Author:
fatimamudassar2009@hotmail.com

Background: Naproxen, an NSAID, works by dropping down the hormones that cause inflammation as well as pain in the body. Naproxen is prescribed for the treatment of pain and inflammation, indicated for the conditions such as arthritis, spondylitis, ankylosing and tendinitis.

Objective: The aim of this study is to compare six different brands of Naproxen Sodium.

Methodology: Quality control parameters: weight variation test, thickness testing, hardness test, friability, disintegration and dissolution test were carried.

Result: Result revealed that all the six brands comply within limits for hardness, weight variation, thickness, friability, disintegration test. Disintegration time for all brands was within 15 minutes complying with the USP commendation.

Conclusion: The present findings suggest that all the brands meet the specification for quality control analysis. All the brands were best fitted with weibull model at pH 7.4.

INTRODUCTION

Naproxen is the most widely used NSAIDS for pain and inflammation caused by trauma, infection, auto immune disorders, neoplasms, joint degeneration and other causes [1-3]. By reversibly and non-selectively inhibiting COX isozymes, they exert their effects. It is particularly potent in inhibiting leucocyte migration – may be more valuable in acute gout [4]. The usual dose is 250 – 550 mg twice a day that is recommended dose use for mild pain and inflammation and w/h higher dose used to treat most arthritic disorder [5]. It is orally administered & widely distributed drug and extensively metabolized by liver, having 1/2 of 14 hours. Adverse effects like gastric irritations,

nausea, dyspepsia and bleeding is likely to be observed [6-8].

METHODOLOGY

We have compared different parameters between the six different brands NEOPROX (propionic acid) tablet in order to ensure that a manufactured product adheres to a defined set of quality criteria. Test accomplished in order to conduct a comparative study between dualistic diverse brands of active naproxen, available in local market of Karachi, Pakistan, tested for subsequent physicochemical parameters to provide cost-effective alternative to patients. Following test parameters are accomplished to appraise the physicochemical parameters of accessible brands of naproxen.

Weight variation

Variation in weight was tested on A.N.D Electronic Balance PA214 Weight must be within BP limits. For which 20 tablets of both brand were selected erratically. The percentage weight variation from average tablet weight was calculated. In order to permit weight variation test, the tablet must be within the perimeters of the percentage deviation acceptable by BP. Upper and lower control limit for weight variation is calculated.

Thickness

The degree of compaction of 20 tablet of each brand is evaluated by assessing the thickness of tablets, by using Vernier Caliper.

Hardness

This test is performed on 10 tablets of each of the brands to conclude the asset of tablet when applied stress. A tablet must be hard abundant to tolerate stress. Hardness of both brands is checked on MH-11 Hardness Tester of Galvano Scientific. The hardness values of all tablets were evaluated and average value was calculated besides compared.

Friability

Friability test has been implemented on 10 tablets of each brand of naproxen by endangering to a uniform tumbling motion for specified period of time i.e. 25 rotation/minute for 4minutes in Curio FB-1004. Friability test is done by taking initial and final weight and determining the weight loss.

Disintegration

Disintegration Testing is quality control test done to determine whether capsules or tablets are disintegrating within the appropriate time when retained in a fluid medium. Disintegration assessment for each of the brands was done on CURRO MODE NO DT-0607. A 900 ml beaker was filled with distilled water and temperature was maintained at $37 \pm 2^{\circ}\text{C}$. From each brand, 6 tablets of each brand were designated arbitrarily and placed into the basket rack assembly and linked to the disintegration apparatus. The

disintegration time for both brands is compared with the Pharmacopoeial limit stated in BP.

Dissolution testing

Dissolution studies was performed on six commercially available naproxen sodium film coated tablets using USP Apparatus 2 (paddle method) dissolution medium was 900 ml of phosphate buffer (pH 7.4). The paddle rotation speed was kept at 50 rpm. In all experiments, 5 ml of dissolution sample was withdrawn at 5, 10, 15, 20, 30, and 45 min and replaced with an equal volume of the fresh medium to maintain a constant total volume. Samples were assayed by UV spectrophotometer at 329nm Cumulative percentages of the drug dissolved from the tablets were calculated.

RESULTS & DISCUSSION

This study is based on comparison between six available brands of naproxen sodium 550mg that are available for consumer use. Results were found to be within limits. Mean weight of 561 mg, all the brands fall in 5%range of mean thickness of 17.85mm. Mean hardness is found to be 6.667kg, hardness limit for immediate release tablets is 4-10kg so all the brands comply with specification. In friability test, %friability is found to be in range of 0.426% to 0.65 the range is up to 1%, so all the brands comply with specification. All the six brands averagely took.

Evaluation for release kinetics

In current study drug release of six brands of naproxen sodium 550mg is compared with reference drug using phosphate buffer ph 7.4.

Model independent method

In this study we compared the reference brand and the tester brands. We also evaluated the reference drug with test drug.

Difference factor (f1) and similarity factor (f2) of reference drug with all test drug formulations at phosphate buffer ph 7.4. Consecutive values of difference factor (f1) and similarity factor (f2) using phosphate buffer ph 7.4 were in range of

2.65-7.78 and 59.20-81.50 respectively (Table 1) (Figure 1).

Table 1. Difference factor (f1) and similarity factor (f2) of reference drug with all test drug formulations at phosphate buffer pH 7.4.

f1	Ref.1	f2	R	ef.1
Test.1	4.11	Test.1	72	.49
Test.2	7.78	Test.2	59	.20
Test.3	7.21	Test.3	61	.72
Test.4	5.15	Test.4	69	.88
Test.5	2.65	Test.5	81	.50
Test.6	6.73	Test.6	59	.87
Mean f1	4.08	Mean f2	73.67	Accept

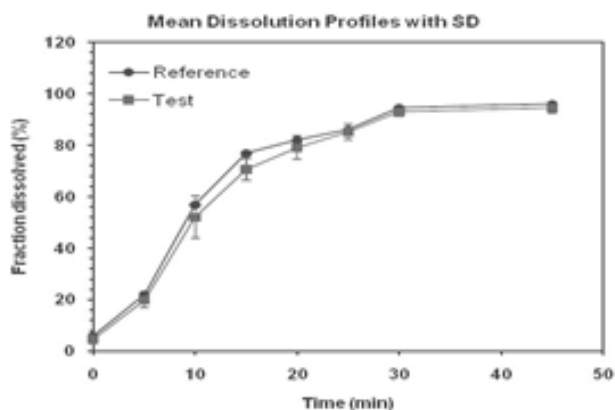


Figure 1. Difference factor (f1) graph of reference drug with test drug.

Model dependent method

For First order kinetics model r2 value for Ph 7.4 was in range of 0.9631-0.9763. For Higuchi with the kinetics at pH 7.4 r2 value were in range of 0.8918-0.9405. For Hixson-Crowell law r2 value were in range of 0.9584 - 0.9866. Drug release analysis for test 01- test 06 were best fitted with weibull model at pH 7.4 as r2 value were in range of 0.9618-0.9937. Table 2 and Table 3 (Figure 2 and 3).

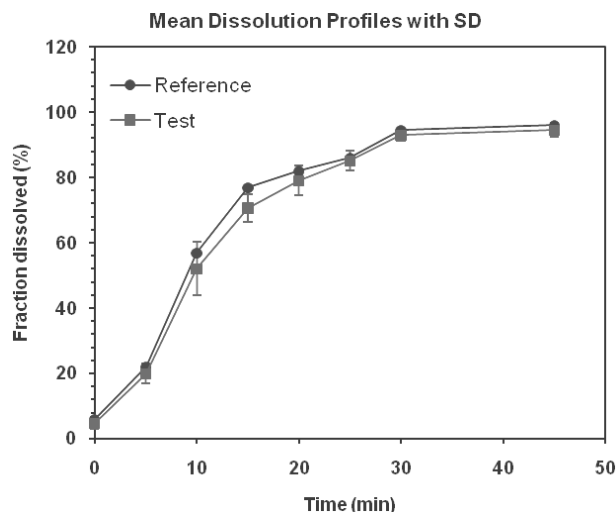


Figure 2. Similarity factor (f2) graph of reference drug with test drug.

Table 2. In vitro release kinetic of naproxen sodium tablets 550 mg at phosphate buffer pH 7.4.

Model	Equation	Parameter	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	MEAN	S.D	RSD
First order	$F=100*[1-Exp(-k1*t)]$	k1	0.090	0.068	0.068	0.073	0.080	0.069	0.082	0.076	0.009	11.404
Higuchi with Tlag	$F=kH*(t-Tlag)^{0.5}$	kH	17.037	16.959	17.060	16.516	16.685	16.800	16.944	16.857	0.200	1.188
Hixson-Crowell	$F=100*[1-(1-kHC*t)^3]$	kHC	0.024	0.019	0.019	0.020	0.022	0.019	0.022	0.021	0.002	10.472
Weibull	$F=100*\{1-Exp[-(t^\beta)/\alpha]\}$	α		37.828	34.621	20.061	23.610	35.740	23.368	27.922	7.794	27.912
		β	1.238	1.342	1.314	1.140	1.245	1.333	1.251	1.266	0.071	5.574

Table 3. *In vitro* correlation of naproxen sodium tablets 550 mg at phosphate buffer ph 7.4.

MODEL	Parameter	r2	r2	r2	r2	r2	r2	r2
First order	k1	0.9763	0.9761	0.9694	0.9631	0.9727	0.9740	0.9723
Higuchi with Tlag	kH	0.8935	0.9405	0.9334	0.8978	0.8834	0.9220	0.8918
Hixson-Crowell	kHC	0.9784	0.9866	0.9785	0.9584	0.9747	0.9829	0.9751
Weibull	$\alpha \beta$	0.9824	0.9937	0.9840	0.9618	0.9789	0.9895	0.9795

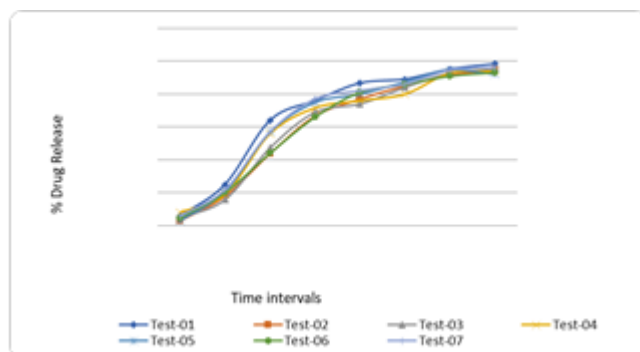


Figure 3. The % Cumulative drug release of reference drug with all brands available in market at different time intervals.

CONCLUSION

The available brands in local market of Karachi Pakistan are found similar in its physicochemical parameters and within the specified limits for quality control range and can be a substitution in case of any non-compliance. Results of this study are helpful in predicting the release behavior of different product.

REFERENCES

1. Johnson ES, Ratcliffe DM, Wilkinson M. Naproxen sodium in the treatment of migraine. Cephalalgia. 1985; 5(1):5-10.
2. Sances G, Martignoni E, Fioroni L, Blandini F, Facchinetti F, Nappi G. Naproxen sodium in menstrual migraine prophylaxis: a double-blind placebo controlled study. Headache: The Journal of Head and Face Pain. 1990; 30(11):705-9.
3. Csapo AI, Pulkkinen MO, Henzl MR. The effect of naproxen-sodium on the intrauterine pressure and menstrual pain of dysmenorrhic patients. Prostaglandins. 1977; 13(1):193-9.
4. Suprpto K, Reed S. Naproxen sodium for pain relief in first-trimester abortion. Am J Obstet Gynecol. 1984; 150(8):1000.
5. Capone ML, Tacconelli S, Sciulli MG, Anzellotti P, Di Francesco L, Merciaro G, Di Gregorio P, Patrignani P. Human pharmacology of naproxen sodium. J Pharmacol Exp Ther. 2007; 322(2):453-60.
6. Segre EJ. Naproxen sodium (Anaprox): pharmacology, pharmacokinetics and drug interactions. J Reprod Med. 1980; 25(4 Suppl):222-5.
7. Sevelius H, Runkel R, Segre E, Bloomfield SS. Bioavailability of naproxen sodium and its relationship to clinical analgesic effects. Br J Clin Pharmacol. 1980; 10(3):259-63.
8. Tripathi KD. Essentials of medical pharmacology. JP Medical Ltd; 2013.