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In-Vitro Quality Evaluation of Marketed Naproxen 500 mg Tablets in Bangladesh

Md. Shahin Sarker[1]*, Shamsun Nahar[1], and Mir Imam Ibne Wahed[2]

[1]Department of Pharmacy, Faculty of Biological Science and Technology, Jashore University of Science and Technology, Jashore-7408, Bangladesh; and [2]Department of Pharmacy, Faculty of Science, University of Rajshahi, Rajshahi-6205, Bangladesh.

*Correspondence: sarkershahin@just.edu.bd

ABSTRACT

The quality of pharmaceutical finished dosage forms is one of the major concerns to pharmaceutical industries. Tablet dosage form of any pharmaceutical company goes through many research studies and experiments to maintain the proper quality standards. This study was conducted to investigate the quality of Naproxen 500 mg tablets which are manufactured in Bangladesh. Different physical parameters like weight variation, thickness, friability as well as and dissolution profile studies were conducted to evaluate the quality of the Naproxen tablets. The tendency of a tablet to chip, crumble or break following compression is called friability. The friability test results were in range of the standard value. The thickness test of all the brands was complied with the standard values except the brand B. The thicknesses of A, B, C, D and E brands are 4.1, 7.1, 6.0 5.32, and 6.1 mm respectively. To ensure quality product a pharmaceutical industry follows the international standards. The average cumulative % of drug release from A, B, C, D and E brands were 98%, 102.85%, 92.24%, 101.11%, and 99.96% respectively.

Keywords: *In-Vitro*, Naproxen 500 mg, Quality evaluation, Investigate, and Physical parameters

INTRODUCTION:

Now-a-days, two anti-inflammatory medications that are available on the market, these are Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) and Steroids. The use of anabolic steroids that can lead to both emotional and physical problems like increased aggressive behavior, mood swings, impair judgment, male-pattern baldness, acne, and liver damage, prostate cancer, increased risk of heart disease, stimulated growth of certain cancers, and other medical problems, also increases the risk of infectious diseases such as hepatitis (Ann *et al.*, 2000). Gynecomastia is a common adverse effect that is associated with anabolic steroid uses and the prevalence rate of 37% in anabolic steroid users (Sharif *et al.*, 2019). Furthermore change in libido appears to be the most common adverse event (approximately 61% of users) reported in a small sample of anabolic steroid users (Qamar *et al.*, 2017).

On the contrary, cyclooxygenases (COX) inhibitors that is commonly called NSAIDs such as ibuprofen, diclofenac, and naproxen, have anti-inflammatory and analgesic and antipyretic properties across a wide range of dosing regimens. There are two types of COX enzymes, COX-1 and COX-2 that differ in their tissue distribution and regulation and serve different biological function (Manivannan *et al.*,

2010). All NSAIDs that inhibit COX are effective for relief of chronic musculoskeletal pain and inflammation in condition such as rheumatoid arthritis (RA) or osteoarthritis (OA), menstrual cramps, backache and arthritis. They also protect the lining of the stomach and intestines from the damaging effects of acid, promote blood clotting by activating blood platelets, and improve normal function of the kidneys. NSAIDS are also used as generalized symptom treatment ranging from arthritis, headache, fever, and gout. So, it can be firmly stated that, NSAID is preferable to steroid medicines due to its non-hazardous properties in human life. Everyday NSAIDs are taken by more than 30 million people worldwide of these, 40% of consumers are older than 60 only 4.5% of the prescriptions are for so-called centrally acting analgesics, namely the opioids (Bacchi *et al.*, 2012).

The objective of this study to evaluate the quality control parameters of Naproxen tablet available in the market. Main focus of this research to the batch to batch variation of Naproxen tablets which are available in the market. Because when tablets are manufactured they comply with the standard quality but after they reach the market they may or may not maintain same quality after a certain period of time.

MATERIALS AND METHODS:

Materials - for these research work five brands of marketed Naproxen were collected from local medicine shop and those were sampled as A, B, C, D, E. A. All others research grade chemical reagents and logistical supports were provided by Pharmaceutical Technology Lab of the Dept. of Pharmacy, Jashore University of Science and Technology, Jashore-7408, Bangladesh.

Weight Variation Test - Weight of a tablet is one of the major indicators of content uniformity. The weight variation test is used prior to a batch release on the other hand, rarely for the drug stability testing (Kim Huynh-Ba, 2009). This test is performed to ensure that all of the tablets in a batch are within reasonable limits of the same potency. A perfect manufacturing procedure would yield a batch of tablets having identical weight and medicament content. To evaluate the weight variation, calculated average weight by Analytical Balance (ATY224, Shimadzu, Japan) of 10 tablets and weighed 10 whole tablets individually.

Thickness Test - Variation in tablet thickness should not be immediately appearing under normal conditions, for obvious reasons of product acceptance by the consumer. In general, tablet thickness is controlled within 5% of standard value (Remington, 2006). Tablets were individually placed horizontally between two jaws of the Vernier Calipers (Shimadzu, Japan). The caliper scale was run to hold the tablet which gave a visual reading of tablet thickness. According to the USP (2007), tablets should have thickness about ± 5mm.

Thickness was calculated by using the following formula:

Thickness = Main scale reading + (Vernier scale reading ×Vernier constant)

Friability Test - The experiment has been started by weighing 10 tablets which is considered as the initial reading. All the tablets have been placed in the drum of Friability Tester (Shimadzu, Japan) and rotate 100 times .The percentage loss has been calculated. It is calculated as initial weight minus final weight divided by final weight multiplied by 100.Weight loss indicate as the percent friability and the loss of weight should not more than 1% (Qiu *et al.*, 2009).

Dissolution Test (Brown and Marques, 2013) **-** The rate of drug absorption is determined by the rate of drug dissolution from the dosage form. Therefore it will usually be important to obtain rapid drug dissolution from the dosage form (Lachman *et al.*, 2018). In dissolution apparatus (Electro-lab) the water tank was filled and temperature was setat 37±0.5ºC. 900 ml of the phosphate buffer was poured into one of the vessels and instruments were run till the set temperature was attained.

The remaining 100 ml of the medium was used as a blank. One of the sample tablets was placed into the vessel and starts the run. Rotate the paddle at 50 revolutions per minute. At the end of the time

specified (5, 15, 30, 45, 60, 90, and 120 min), 10 ml of the sample was collected and filtered. 10 ml of the filtered sample was diluted with the buffer medium. Using the same procedure, as for the blank sample, use the phosphate buffer. Finally the absorbance was measured at 332 nm (BP, 2003).

Statistical Analysis - All statistical analysis was performed by MS Office Excel and Graph Pad Prism software. Excel is quiet a powerful instrument often used in biomedical research as a support for datasets. It does contain some basic statistical analysis and could serve for simple inference.

RESULTS:

Weight variation test: To determine the content uniformity weight variation test is required. The weight variation test results of Naproxen 500 mg tablets are given in **Table 1**.

Table 1: Percentage of Weight Variation of Naproxen 500 mg Tablet

Tablets No.	% Weight Variation				
	Brand-A	Brand-B	Brand-C	Brand-D	Brand-E
1	0.210	0.084	0.58	-1.69	0.18
2	-0.216	0.71	0.25	1.073	-1.72
3	0.007	0.66	0.46	-1.34	1.57
4	-0.360	1.28	0.55	0.169	-2.42
5	0.56	-0.63	-0.076	0.30	1.63
6	-0.58	0.76	0.40	-0.77	-1.22
7	0.95	0.14	-0.03	-1.01	0.22
8	-0.92	0.83	-0.57	3.05	2.32
9	0.39	1.04	-1.22	0.74	-0.40
10	0.41	1.49	-0.31	0.23	0.36

Table 1 provides information about the individual % weight variation of different marketed Naproxen 500 mg tablets. No tablets exceed ±5 % variation.

Thickness Test: Tablets of each brand were randomly selected to conduct the thickness test. Test results were given in **Table 2**.

Table 2: Average Thickness of Naproxen 500 mg Tablet

Brand Name	Average reading of scale (mm)	Reading of vernier scale (mm)	Vernier constant	Average thickness of the tablet
A	4.0	1.0	0.1	4.1
B	7.0	1.0	0.1	7.1
C	5.5	5.0	0.1	6.0
D	5.5	4.0	0.1	5.9
E	6.0	1.0	0.1	6.1

Table 3: Percentage of Friability of Naproxen 500mg Tablet

Brand	Initial weight of ten (10) tablets	Final weight of ten (10) tablets	% Friability
A	7027	7025.9	0.0156
B	6166.9	6162.5	0.0710
C	6698.4	6695.9	0.0075
D	5420.2	5419.00	0.0221
E	5556.1	5553.9	0.0395

Friability Test: Ten tablets each brand of naproxen were selected to conduct the friability test. Test results were given in **Table 3**.

Dissolution Test: One tablet from each brands of naproxen was randomly selected to conduct the tablet dissolution test. Average absorbance of standard naproxen was found 0.327 nm. Test results of the different marketed brand of naproxen are given in **Table 4**.

Table 4: *In-vitro* dissolution profile of different marketed brands of Naproxen 500 mg tablets

Time (Minute)	Cumulative % drug release				
	Brand-A	Brand-B	Brand-C	Brand-D	Brand-E
5	76.14	91.13	70.33	73.08	111.0
10	100.30	104.28	70.94	97.55	89.60
15	103.97	104.28	80.42	98.16	95.40
30	97.55	100.90	102.75	85.01	91.74
45	96.94	112.20	105.19	108.56	111.0
60	99.38	105.89	104.89	100.61	100.0
90	102.75	105.19	101.22	103.05	96.02
120	107.03	99.08	102.14	134.86	104.89

The average cumulative % drug release from A, B, C, D and E brands were 98%, 102.85%, 92.24 %, 101.11% and 99.96% respectively. According to BP all the tablets passed the specification. The dissolution tolerance in the USP is not less than 75% dissolved in 45 minutes. BP specifies that after 45 minute 95-105 % of the active ingredient of Naproxen must dissolute into the suitable medium.

DISCUSSION:

Quality Control is an essential function in the pharmaceutical industry. Drug manufacturers must have needed to ensure that their final products are consistent, safe, effective and predictable. During this study, weight variation which is the key to controlling crushing strength and friability of tablet was assessed. The test result revealed that all of the brands of naproxen tablets passed the weight variation uniformity test as specified in the USP (not exceed 5% deviation). Tablet thickness test provides an idea about the compressive strength during compression process.

The highest value of thickness was 7.1 of Brand-B and 6.1 of Brand-E respectively. Difference between the thicknesses of the brands was quite small. Thickness was always an issue when tablets are considered. If the tablet is thicker than it cannot be swallowed by an average person, if the tablet is less thick then it can breakdown easily. So that thickness is important QC test. The friability test is closely related to tablet hardness and is designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping. Conventional compressed tablets that lose less than 0.5 to 1 % of their weight are considered acceptable. In the friability test, all of the tablet brands showed impressive friability values.

From the **Table 3**, we found that the percentage of friability values for all the brands were within acceptable range. Difference between the brands friability percentage was quite small, the highest friability value was Brand-B (0.071) and lowest was Brand-C (0.0075). Dissolution test was performed to determine the rate of release of the drug. In order to be absorbed, a drug must first be dissolved in the fluid at the absorption site. It was found (**Table 4**) that the dissolution of a pure drug can be altered significantly when mixed with various adjuncts during the manufacturing process of solid doses forms. These adjuncts are added to satisfy certain pharmaceutical functions such as diluents, binders, granulating agents, disintegrants and lubricants. These adjuncts can also affect the rate of dissolution. If a tablet contains more than its effective dose than it can cause overdose related complications. If a tablet contains less than its effective dose than it does not give desire effect. Right quantity of active

ingredient in drug is necessary to give the desire effect of drugs.

CONCLUSION:

For the growing human population, pharmaceutical products necessities are increased rapidly. The qualities of these products are the prime concern for the regulatory bodies. Quality control parameters of any pharmaceutical products are the major concern for optimum efficacy and safety. To prevent any contamination or errors quality control studies must be needed. The quality parameters should be followed by the specification of the standards. Most of the tested samples met the quality specifications of BP and USP standards with some exceptions. To draw any conclusion regarding the quality of these brands considering the batch to batch variation more extensive studies should be conducted including *in-vivo* test. To understand their actual therapeutic effectiveness, bioavailability or bioequivalence study is essential. From this study, it is clear that a patient can choose any brands of marketed Naproxen 500 mg tablets whatever the brand is prescribed by the physician.

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CONFLICTS OF INTEREST:

The authors declare that they have no conflict of interests.

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