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In-Vitro Comparative Quality Evaluation of Marketed Cefuroxime 250 mg Tablets in Bangladesh

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ABSTRACT

The study evaluated different quality control parameter of five brands of Cefuroxime 250mg tablets which are already marketed in Bangladesh. Five brands of the drug sourced from different retail outlets to assess the quality assessment and comparison of the tablets using the *in-vitro* release study. The brands were subjected to various official tests including uniformity of weight, thickness test, dissolution tests and cumulative % of drug release and friability test. This research further focuses the requirement of manufacturers to construct quality into their products during manufacture and also sustain the built-in quality from batch to batch in line with the principles of cGMP.

Keywords: *In-Vitro*, Cefuroxime 250mg, Quality evaluation, Comparative, and Physical parameter.

INTRODUCTION

Antibiotic resistance is one of the most common issues in the worldwide due to misuse or over use of antibiotics (Palikhe *et al.,* 2004). According to the previous studies about 20-30% of all antibiotic use is inappropriate resulting in increased adverse effects, cost of treatment and upraises antimicrobial resistance (Steinman *et al.,* 2003; Islam *et al.,* 2020, and Uddin *et al.,* 2014). Studies reveled that, third world countries double their expenditure on drugs every four years whereas Gross Domestic Product (GDP) doubles in every sixteen years (Mohanty *et al.,* 2010)

Beta-lactam antibiotics are one of the most commonly prescribed drug classes with numerous clinical indications. Cephalosporin's are the beta-lactam antibiotics which contain a 7 amino-cephalosporanic acid nucleus and side-chain containing 3, 6-dihydro-2 H-1, 3- thiazine rings (Harding *et al.,* 1984). Cephalosporins are divided into five classes or generations (Alam *et al*., 2017)

Cefuroxime is the 1-acetyloxyethyl ester of cefuroxime belongs to the second generations of cephalosporins (Harding *et al.,* 1984). Protein binding range of cefuroxime is approximately 30% and volume of distribution of about of cefuroxime is about 171 (Foord, 1976). Distribution of cefuroxime into body fluids and tissues is variable, however, it can penetrate well (35-90%) into the tonsil tissue, sinus tissue, and bronchial mucosa (Perry *et al.,* 1996). Adverse effects of cefuroxime are primarily gastrointestinal in nature, including diarrhea/loose stools (3.7%), nausea (2.6%), and vomiting (2.6%) (Glaxo Wellcome Inc., 1995; McEvoy *et al.,* 1997)

The primary objective of this study to evaluate the quality control parameters of Cefuroxime tablet available in the market. When tablets are manufactured, each and every tablet must have needed to 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 & METHODS

Chemicals and Reagents

All research grade chemical reagents (NaOH, Na_2HPO_4, $NaHPO_4$ and distilled water) and logistical supports were provided by Pharmaceutical Technology Lab of the Dept. of Pharmacy, Jashore University of Science and Technology, Jashore-7408, Bangladesh.

Sample Collection

To perform this research study five different brands of Cefuroxime tablets were purchased from the local medicine shop of Jashore city in Bangladesh and coded as A, B, C, D and E. All brands were labeled to contain 250 mg of cefuroxime per tablet.

Study Design

Comparative *in-vitro* quality control parameters among five commercial pharmaceutical brands were studied through the evaluation of weight variation, tablets thickness, friability, and dissolution profile.

Weight Variation

To evaluate weight variation 10 tablets of each brand were weighed individually and also weighed whole tablets using a digital analytical electronic balance Shimadzu. This test is performed to ensure that all of the tablets in a batch are within reasonable limits of the same potency (Sarker *et al.,* 2019). A perfect manufacturing procedure would yield a batch of tablets having identical weight and medicament content.

Thickness Test

One of the tablets from each brand was randomly selected for thickness test. In general, tablet thickness should be controlled within 5% of standard value. Tablets were individually placed horizontally between two jaws of the Vernier Calipers (Shimadzu, Japan). According to the guideline of 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 one tablet which is considered as the initial reading. All the tablets have been placed in the drum of Friability Tester (Shimadzu, Japan) and rotate at the speed of 25rpm for 4 minutes. During this test loss of weight indicate the percent friability and the loss of weight should not more than 1% (Qiu *et al.,* 2009).

Dissolution Test

In dissolution apparatus (Electro-lab) the water tank was filled and temperature was set at 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 100 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 (Sarker *et al.,* 2018). 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 280 nm.

Statistical Analysis

Statistical analysis regarding this research was performed by MS Office Excel and Graph Pad Prism software.

RESULTS

Weight variation test is required to determine the content uniformity of tablets. The weight variation test results of Cefuroxime 250mg is given the **Table 1** which provides information about the individual % weight variation of different marketed Cefuroxime 250mg tablets. No tablets exceed ±5 % variation. Tablets of each brand were randomly selected to conduct the thickness test. Test results were given in **Table 1**. From the results it was obtained, that the deviation does not exceed ± 5% based on the calculation. Ten tablets each brand of Cefuroxime were selected to conduct the friability test. Test results were given in **Table 1**.

The dissolution studies of cefuroxime were performed in phosphate buffers (pH 4.5 and 6.8) according to US-FDA (US FDA CDER, 1997).

Cumulative drug release was found 70.24%, 67.78%, 73%, 77% and 77.16% for the brands A, B, C, D and E respectively at 120 minutes. According to previous study, cefuroxime is a BCS class II drug with poorly water solubility and by using of appropriate solubility enhancing agent (surfactant) and disintegrator can increase the dissolution rate of the active component (Woo *et al.,* 2000).

Table 1: In-Vitro QC parameter evaluation of different brands of Cefuroxime 205mg tablets

Brand of Cefuroxime tablets	Weight variation (%)	Average thickness (mm)	Percentage of Friability (%)	Cumulative drug release (%)
A	0.126	4.215	0.079	70.24
B	0.196	4.475	0.060	67.78
C	0.203	5.065	0.107	73.00
D	0.049	5.073	0.096	77.00
E	0.048	4.485	0.032	77.16

DISCUSSION

In the present study, pharmaceutical evaluation of various brands of cefuroxime by applying different approaches to investigate quality control parameter. 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 cefuroxime tablets passed the weight variation uniformity test as specified in the USP (not exceed 5% deviation).

Differences between the thicknesses of the brands were found quite small. If the tablet is thicker than it cannot be swallowed by an average person, if the tablet is less thick then it can breakdown more easily. So that uniform thicknesses of all brands of any tablets is needed to ensure the quality. The friability test is designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping and it is also closely related to tablet hardness. Conventional compressed tablets that lose less than 0.5 to 1 % of their weight are considered acceptable. In the friability test, the entire tablet brands showed impressive friability values.

In-vivo bioavailability of drugs, particularly for those drugs which are belonging to class II type drugs is the reflection of the dissolution profile. These drugs have low solubility and high permeability (Yuksel *et al.,* 2000). Dissolution test results of the different marketed brand of cefuroxime tablets exerted quite impressive value. Highest cumulative drug percentage of drug release was found in Brand-E (77.16%) and lowest one was Brand-B (67%) (Israr *et al.,* 2016). This proves that the differences among the brand is quite small so that a patient can easily choose any of the marketed brands of Cefuroxime 250mg tablets which are available in Bangladesh.

CONCLUSION

The *in-vitro* physical and chemical evaluation of selected commercial brands of Cefuroxime 250mg tablets in Bangladesh passed the quality according to USP and BP requirements. As quality control parameters are related to pharmacological action of the drug, a high quality tablet should meet all the standard quality parameter for getting its proper therapeutic response. However, despite the variation most drug products are within the official limit. It reflects that these formulations definitely producing desired effects as antibiotic. So the prescribing patterns should be changed depending upon the socio-economic status of patients.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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