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Comparative Analysis of *In vitro* Quality Parameters of Different Brands of Marketed Ciprofloxacin Tablets Available in Bangladesh

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aim: Ciprofloxacin is a broad-spectrum antibiotic under the group of drugs called fluoroquinolones. It is extensively being manufactured and marketed drug by many national and multinational pharmaceutical companies. The purpose of this study was to compare the quality of different brands of ciprofloxacin 500mg tablets available in Bangladesh using quality characteristics such as weight variation, hardness, thickness, friability, disintegration time, and dissolution profile.
Methodology: The tablets' overall quality criteria, such as weight variation, hardness, thickness, diameter, friability, disintegration time, and dissolving profile, were evaluated using established protocols. An electric analytical balance was employed to measure weight variation. An automated hardness tester was used to determine the hardness, thickness, and diameter. A friabilator was used to determine the degree of friability. A disintegration equipment and a dissolution tester were used to examine the disintegration time and dissolution profile, respectively.
Results: In this study, all the values were compared with the standards. All brands had been passed for the weight variation test, because no tablets surpass the ± 5 % weight variation. The weight variation range was from 714.57±4.08 mg (brand C) to 837.92±7.49 mg (brand E). In hardness testing procedure, all brands of ciprofloxacin 500mg tablets were within the specified limit. The average hardness of the items ranges from 11.11±1.44 kgF to 19.26±2.20 kgF respectively.

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The five brand's percentage friability was less than 1%, indicating that they met the requirements. The lowest friability (0.015 %) was found in Brand E, while the highest friability (0.032 %) was found in Brand B. Within 10 minutes, the entire trademark had disintegrated, indicating that they had met the requirements. Brand E had the quickest disintegration time (5.35±0.49 minutes), while brand B had the slowest (9.12±0.88 minutes).All brands had a dissolution rate of 83.56% for A, 95.84% for B, 91.15% for C, 84.46% for D and 88.97% for E, all those were within 60 minutes in dissolution testing. The five brands' assay was within the specified limit, indicating that they met the requirements

Conclusion: In conclusion, the present study of evaluating quality control parameters revealed that all of the leading brands of this tablet comply the quality control parameters as per pharmacopoeial specifications. Further work is recommended on bioequivalence of these tablets.

Keywords: Ciprofloxacin 500mg; disintegration test; dissolution test; friability; hardness.

1. INTRODUCTION

In today's medicine, antibiotics are one of the most commonly prescribed medications. By killing or suppressing bacteria, they are used to treat bacterial infections [1]. Ciprofloxacin belongs to the fuoroquinolone class of antibiotics [2]. The Food and Drug Administration (FDA) approved this drug in 1987 as the first oral broad-spectrum antibiotic for use in the United States [3]. It's one of the most important pharmaceuticals in the basic health-care system, and it's on the WHO's list of essential medicines [4]. It's commonly used to treat urinary tract infections, lung infections, infection of the bones and joints, endocarditis, gastroenteritis, malignant otitis, gastrointestinal cellulites, and anthrax, among other illnesses [5].

For the safety of patients, high-quality medicine is an important requirement. Oral tablets deliver a medicine in a specific and defined amount through the gastrointestinal system to improve therapeutic effect at the desired site of action. Weight variation, hardness, friability, disintegration time, dissolution profile, and other in vitro quality control characteristics are used to verify the quality of drug products [6]. Furthermore, quality control parameters of tablet also are useful tools for maintaining consistency in batch-to-batch manufacturing and it should be performed for all drug products. All of these parameters are closely related. Absorption and bioavailability of the drugs are affected by these parameters. [7].

If a drug is substandard or counterfeit and does not comply with the standard specification can cause various kinds of problems. WHO has reported that around 10% of the worldwide pharmaceuticals market consists of counterfeit drugs, but in case of developing countries, this assessment rises to 25%, and in certain countries, it may go beyond 50% [8]. FDA stated that in poor countries, about 25% of the consumed pharmaceutical products are substandard or counterfeit [9]. In Bangladesh, 25 children were died after administering paracetamol syrup due to the presence of poisonous diethylene glycol, in 2009. [10]. In 2012, eleven people were killed by contaminated steroidal drugs and another one hundred people were sick in the US [11]. WHO estimated that 28% of antibiotic and 20–90% of antimalarial drugs were unsuccessful in quality specifcations [12]. Moreover, if the antibiotic cannot reach the therapeutic level in the body, it might be the reason for the development of drug resistance which is a major problem of antibiotics [13].

To avoid the negative consequences of substandard goods and to assure the safety and efficacy of pharmaceuticals, pharmaceutical quality must be consistent and repeatable from batch to batch [14]. Drug makers are obligated to test their goods during and after manufacturing, as well as at various intervals throughout the product's shelf life [15].Since ciprofloxacin is widely used antibiotic in Bangladesh, the objective of this work is to find out current status of the quality of the marketed ciprofloxacin tablet available in Bangladesh and whether different brands of ciprofloxacin preparations meet the BP or USP specification of different pharmaceutical parameters such as weight variation, hardness ,thickness, friability, disintegration and dissolution for confirming of proper drug release, absorption from the GIT and optimum therapeutic action of the drug. This work will also raise awareness among the health practitioners as well as drug control authority so that pharmaceutical manufacturers are forced to produce quality medicine. Consequently, it will provide postmarketed product quality information on the

examined brands, reflecting the necessity for more field monitoring efforts to combat against the global threat of low quality drugs as well as the concomitant risks of antibiotic resistance.

2. MATERIALS AND METHODS

2.1 Study Design

Some in-vitro quality control parameters, including weight variation, hardness, thickness, friability, disintegration time, dissolution profile and assay, were studied for comparing five commercial brands of ciprofloxacin 500 mg tablets available in the Bangladesh's market.

2.2 Materials

Legally registered five leading brands of marketed ciprofloxacin 500 mg tablets collected from local medicine shop which was leveled as A, B, C, D, and E were used during this study. The standard ciprofloxacin powder was obtained from the Orion Pharmaceutical Ltd, Gazipur, Bangladesh. All other research grade chemical reagents and logistical supports were provided by Pharmaceutical Technology Lab of the Department of Pharmacy, Comilla University, Cumilla-3506, Bangladesh. Working standard, United State pharmacopeia & British pharmacopoeia were used as a reference for the experiment. All used reagents or chemicals like potassium dihydrogen orthophosphate and sodium hydroxide pellets were of analytical grade. Distilled water was used throughout the work.

2.3 Methods

Following in vitro quality control tests were performed for the evaluation of all the ciprofloxacin 500 mg tablet brands in this study.

2.3.1 Visual Inspection

The thickness of tablets (chosen at random) was measured using a Vernier caliper, as well as visual characteristics such as form, size, and color of various tablet brands. Table 2 summarizes the results. All of the brands tested had uniform thickness and no flaws in color homogeneity, coat integrity, or other factors.

2.3.2 Weight variation test

For making sure the same dose of drugs between different brands, this test is performed. Twenty tablets from each brand were selected and weighed using an Electronic balance, then each tablet was weighed individually, and then comparing the individual tablet weights to the average. The weight variation was calculated from the difference between these two weights. The percent of weight variations for all brands were determined in the same way. According to the United State Pharmacopeia (USP) standard, to pass this test, there should not be more than two tablets deviating from the average by not more than ±5% and none deviated by more than twice of ±10 % [16,17,18].

2.3.4 Hardness and thickness test

Ten tablets were selected from each brand and subjected to Tablet Hardness Tester (8M, Dr Schleuniger, Switzerland). The force applied to the edge of the tablet was gradually increased by moving the screw knob forward until the tablet was broken and the pressure at which each tablet crushed was recorded. Hardness and mean hardness were calculated for each brand. The minimum adequate value of hardness for uncoated tablet (crushing strength) is 4 kg or above, while the optimum hardness for coated tablets is 10-20 kg [19]. The hardness of tablets is very crucial to resist mechanical shocks during the different phases of manufacturing, handling, packaging and transporting [20].

For thickness test, thickness of 10 tablets for each brand was determined by using O-150MM×0.05/6" × 128" Slide Calipers (UK) and their respective average values were calculated.

Table 1. Brand selected for analysis

Sl. No	Brand Name	Mfg. Date	Exp. Date
1	Brand A	Sep 2019	Sep 2022
2	Brand B	March 2020	March 2023
3	Brand C	June 2019	June 2022
4	Brand D	Dec 2019	Dec 2022
5	Brand E	Dec 2019	Dec 2022

Table 2. Visual parameters

Brand Name	Color	Shape	Texture	Thickness (mm)
A	White	Capsule	Smooth	7.83±0.05
B	Green	Capsule	Smooth	5.38±0.07
C	White	Circle	Smooth	5.17±0.05
D	White	Oval	Smooth	5.6±0.06
E	Pink	Capsule	Smooth	5.87±0.05

2.3.5 Friability test

Friability test estimates the influence of transporting tablets from the manufacturer to consumer, as no drug is anticipated to lose more than 1% of its weight after testing to withstand attrition while rough handling and transportation [21]. It can adversely affect the tablet appearance, weight variation and content uniformity [22].

In order to accomplish this process, twenty tablets of each ciprofloxacin 500 mg brand were weighed initially and then subjected to abrasion using a Friabilator. The Friabilator was programmed to turn 100 times in 4 minutes. The tablets were then withdrawn from the Friabilator and reweighed after being dusted. The friability was calculated by measuring the difference in weight according to the following equation [23]:

% Friability (f) = (Initial Weight – Final Weight)/ Initial weight × 100

2.3.6 Disintegration test

In a 1000ml beaker, 900 mL distilled water was added, and the beaker was inserted inside the gadget. One Ciprofloxacin pill was placed in each basket rack tube, a plastic disk was placed over each tablet, and the basket rack was precisely positioned into the beaker. A motor-driven mechanism kept the temperature at 37± 2 °C while moving the basket up and down a distance of 5-6 cm at a rate of 28-32 cycles per minute. The disintegration time and average disintegration time were calculated after all of the Ciprofloxacin tablets passed through the sieve. To meet USP-NF requirements, the tablets must disintegrate within 30 minutes and all particles must pass through a 10-mesh screen. If there is any residue left, it must be a soft mass with no discernible firm core [24,25].

2.3.7 In-vitro dissolution test procedure

The USP paddle method (Apparatus II) was used for undertaking dissolution test of Ciprofloxacin tablet at speed of 100 rpm. About 900 ml of 0.1N hydrochloric acid was filled into 1000ml beaker of dissolution apparatus. The dissolution medium was heated up to 37.0± 0.5 ºC by using an auto heater. One Ciprofloxacin tablet was placed into the beaker. 5ml of the dissolution medium were withdrawn from beaker at interval of 5, 10, 15, 30, 45, 60 minutes which was replaced with another 5ml fresh dissolution medium, & then withdrawn solution was filtered through filter paper. The filtered solution of the sample was diluted with the dissolution medium (100 fold dilutions) and absorbance readings were taken with UV/Visible Spectrophotometer (UV-1800, Shimadzu, Japan) at wavelength of 276 nm. Working standard solutions of ciprofloxacin were also prepared using dissolution medium and absorbance was determined. 0.1N HCl was used as a blank. The concentration of each sample was determined from calibration curve and the percent of drug release at each time was calculated. According to USP-NF, tablets comply with this test if not less than 75% dissolves in 45 min. According to BP tablet comply with this test if not less than 80% dissolves in 45 min [24,26].

2.3.8 Assay determination

Potency analysis of tablets helps to determine the strength of content of drug in a dosage form. Firstly, Ciprofloxacin 100mg ciprofloxacin powder was taken in a 100 ml volumetric flask added with distilled water and dissolved it. The volume was adjusted to 100 ml to get 1000µg/ml of standard stock solution. Then 10 ml of the stock solution was taken and again diluted to 100 ml to make concentration of 100 µg/ ml. Then a series of standard solution of standard ciprofloxacin eg, 2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml, 10µg/ml, 12µg/ml, 14µg/ml, 16µg/ml, 18µg/ml, and 20µg/ml were made with suitable dilution and check for Absorbance at 276 nm against a blank for each solution by UV- Visible Spectrophotometer (UV-1800, Shimadzu, Japan). A standard straight line graph was found by plotting absorbance values on Y-axis and concentration values on X-axis. For this test, tablets from each brand were weighed and finely

powdered. The powder equivalent to 100 mg of Ciprofloxacin was taken and dissolved in Distilled Water. Flasks were subjected to sonication to dissolve the powdered material. Then the solution was filtered. The filtrate was suitably diluted to obtain 100 µg/ml concentration for each brand. The absorbance of each brand was measured at 276 nm against the blank after 4 ml of each brand was built up to 100 ml with 0.1 M HCl [15]. Finally, the potency of ciprofloxacin was determined. The content of ciprofloxacin should not be less than 90% and not more than 110 percent according to USP-NF, while the content should not be less than 95% and not more than 105 percent according to BP. [26]

3. RESULTS AND DISCUSSION

Various quality control tests were performed on all ciprofloxacin brands during this investigation, covering weight variation, hardness, thickness, friability, disintegration, dissolution test, and assay determination.

3.1 Weight Variation

Weight variation measures the content uniformity of the tablets. Because of many reasons, tablets may be excessively overweight or underweight. Patients receiving the overdosed or underdosed tablet, appearances unpredictable therapeutic response [27]. As represented in Fig. 1, brand E showed the highest deviation of 837.92±7.49 mg, no tablet crossed the limit and brand C showed least deviation of 714.57±4.08 mg among all the five brands. The weight variation of the tablets all brands used in this study complied with the standard specification. As it is established from USP specification that the limit of deviation is ±10% for tablets weighing 130 mg or less, ±7.5% for tablet weighing more than 130 mg to 324 mg and ±5% for tablet weighing more than 324 mg.

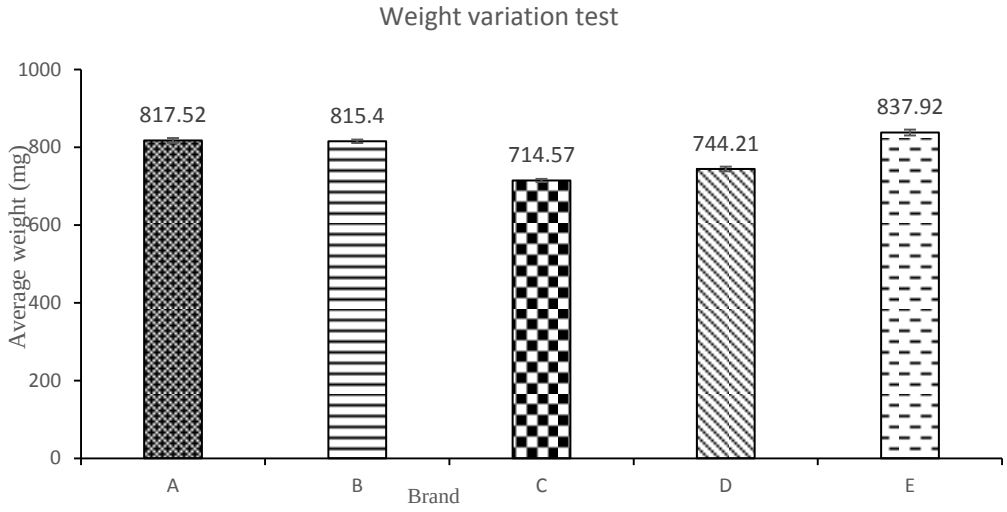

Fig. 1. Weight variation of five brands of ciprofloxacin 500mg tablets

Table 3. Hardness, thickness and friability of five Brands of ciprofloxacin 500mg tablets

Brand	Hardness(kgF)	Thickness(mm)	Friability(%)
A	14.74±1.49	7.83±0.05	0.024
B	19.26±2.20	5.38±0.07	0.032
C	11.11±1.44	5.17±0.05	0.023
D	10.31±0.80	5.6±0.06	0.031
E	11.72±1.11	5.87±0.05	0.015

Values are expressed as mean ± SD

3.2 Hardness and Thickness Test

The results of the hardness test are exhibited in Table 1. Hardness is an essential in vitro parameter which affects disintegration time. The higher the hardness of the tablet, the higher the disintegration time. For adequate quality products optimum hardness of the product must be ensured. As a result, suitable tablet hardness and powder resistance are required for high-quality products [28]. All the values of hardness test meet the standard specification. Brand B had the highest hardness value (19.26±2.20 kgF) and brand D had the lowest hardness value (10.31±0.80 kgF). In thickness test, band A had the highest thickness value (7.83±0.05mm) and brand C had the lowest thickness value (5.17±0.05mm).

3.3 Friability Test

Friability discloses information about the mechanical strength of the tablets [29]. The results of friability test are exhibited in Table 3. Among five brands, brand-B showed maximum friability (0.032%) whereas brand-E showed minimum friability (0.015%). The obtained result of friability ensures that all the tablets of each brand were mechanically stable [23].

3.4 Disintegration Test

The drug must be in solution form, before absorption take places. The first important stage for most of the tablets toward solution is the breakdown of the tablet into smaller particles, this process is known as disintegration [30]. Disintegration must be closely interrelated to dissolution and bioavailability of a drug [31]. The result of disintegration time test is shown in Fig. 2. From the result it is found that disintegration time for all brands were under 30 min. As per results shown, Brand E had lowest disintegration time and Brand B had highest disintegration time. All of the brands meet the Standard requirements. Similar findings were reported by Kahsay [32].

3.5 Dissolution Test

The tablet's absorption is determined by how quickly it dissolves in solution after ingestion. The dissolution of the tablet is completely responsible for tablet absorption. Prior to absorption, dissolution is a rate-limiting phase. The dissolving rate is proportional to the tablet's efficacy as well as the bioavailability differential between different formulations [33]. The result of dissolution rate is presented in Fig. 3. Brand B had the highest dissolution rate (95.84%) and brand A had the lowest dissolution rate (83.56%).From the obtained figure, it is obvious that all the brands complied with the standard specification.

3.6 Assay Determination

Assay determination of a drug is very essential for determining the presence, absence, or quantity of one or more ingredients in a dosage form [34]. Brand B had the highest drug content (101.12%) and brand A had the lowest drug content (96.45%).

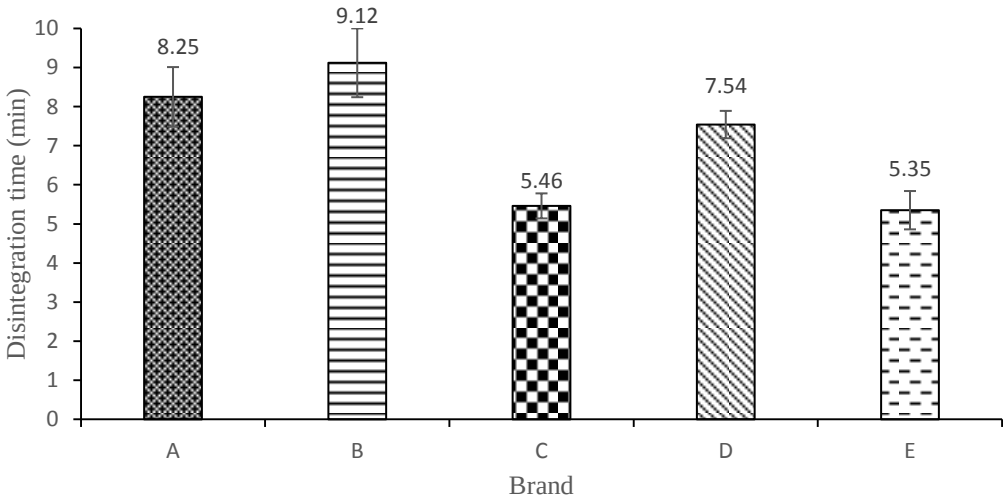

Fig. 2. Disintegration time of five brands of ciprofloxacin 500mg tablet

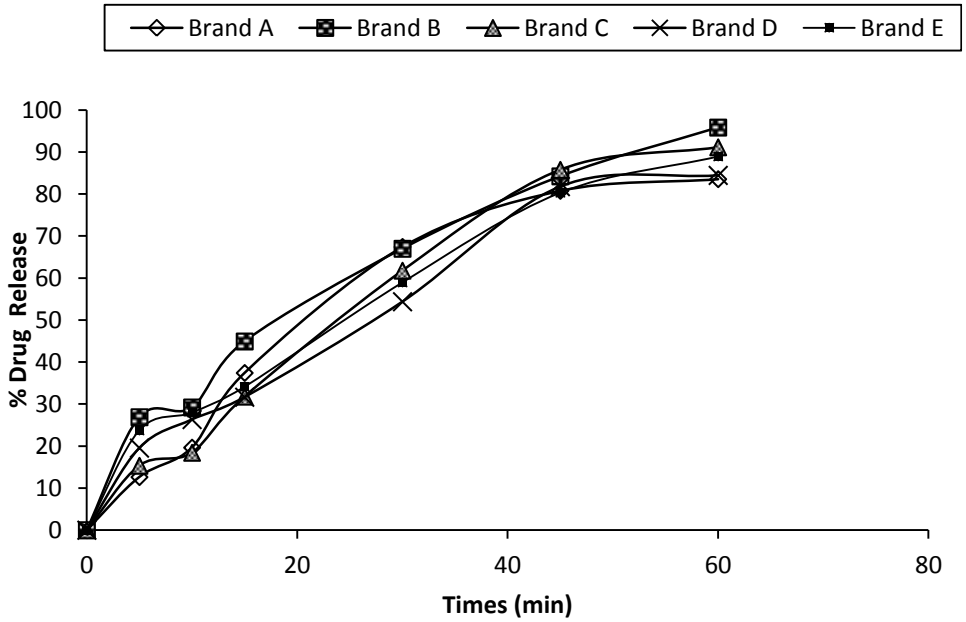

Fig. 3. Dissolution profile of five brands of ciprofloxacin 500mg tablet

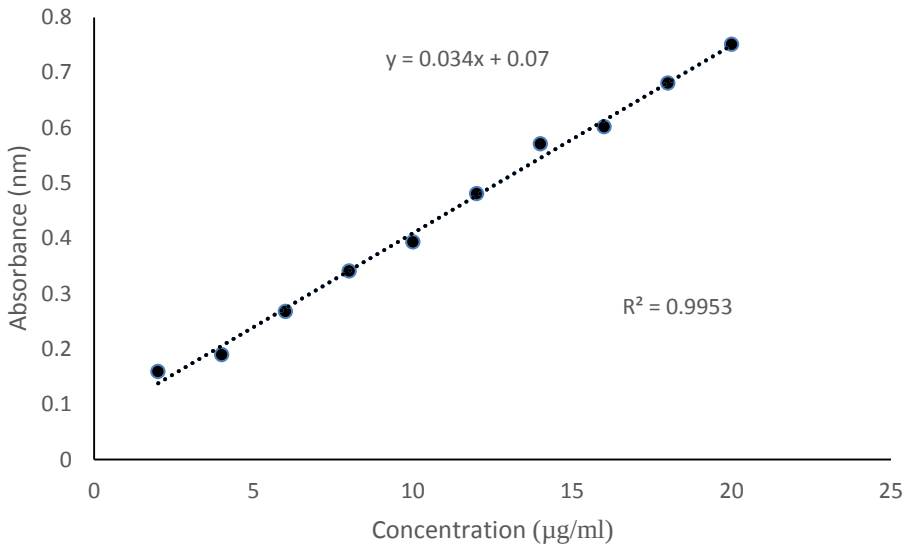

Fig. 4. Standard calibration curve for ciprofloxacin

Table 4. Assay of five Brands of ciprofloxacin 500mg tablets

Brand	Assay (%)±SD
A	96.45±0.98
B	101.12±0.34
C	99.52±0.86
D	97.88±0.77
E	98.23±0.69

Values are expressed as mean ± SD

4. CONCLUSION

This study attempted to assess the quality and physicochemical equivalence of some ciprofloxacin tablets manufactured by some of the world's leading pharmaceutical companies. The physicochemical parameters evaluation displayed that all the tablets from all brands met the quality specification with respect to weight variation, hardness, friability, disintegration, dissolution and assay. It reflects that these formulations are producing with the desired effects as an antibiotic. Hence, based on the in vitro results, it can be stated that any of the ciprofloxacin tablets marketed in Bangladesh might be interchangeable, although in vivo testing is required for final remarks regarding the quality of marketed brands of ciprofloxacin tablets.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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