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Article

Comparative evaluation of quality control parameters between commercially available and formulated tablets of Fexofenadine hydrochloride 120 mg

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Abstract

Fexofenadine hydrochloride is a second-generation antihistamine that works by blocking H2 receptors and is primarily indicated for allergic rhinitis. To satisfy the desired pharmacological effect it is important for a drug to comply with all the specifications of the guideline. This study has been conducted to evaluate the quality parameters of commercial drugs and establish a comparative screening of commercial drugs with the formulated ones. Fexofenadine HCl was formulated in the laboratory setup and one particular brand was selected and compared with the formulated drug. The quality parameter was checked by performing potency and dissolution test, weight variation test, thickness hardness-diameter determination, disintegration time detection and friability test. The test result has shown that formulated dug has a similar potency to the commercial drug with the commercial drug achieving a potency of 97.5%. The values obtained from the tests were used to analyze the degree of conformance of commercially available drugs to the USP specification that represents the quality of both commercially available and formulated fexofenadine hydrochloride 120 mg tablets. The results found in the experiment were used to find out the degree of compliance of the drugs to the USP specification which indicates the quality of Fexofenadine hydrochloride. All the parameters comply with the USP specifications which ensure the desired pharmacological effect.

Keywords: Commercial drug, Formulated drug, Fexofenadine hydrochloride, Quality control parameters, Quality of medicine

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Introduction

The drug Fexofenadine Hydrochloride has become one of the most commonly encountered OTC (over-the-counter) drugs during the new normal. Even prior to the pandemic, the drug was one of the most popular drugs for the treatment of allergic conditions including cold allergies. Fexofenadine hydrochloride belongs to the therapeutic class of second-generation antihistamines that antagonizes the effect of histamine to treat several allergic symptoms such as allergic rhinitis, runny nose, sneezing, etc. (Türkmen et al., 2018). The drug is popular due to its avoidance of adverse reactions associated with the central nervous system because of its unavailability to cross the blood-brain barrier. These drugs have more specificity and selectivity toward receptors compared to first-generation antihistamines (Podder et al., 2023). The drug mimics the structure of histamine and binds to histamine receptors (Parisi et al., 2020). This prevents the histamine from producing their action as they cannot bind to it. The blocking of receptor also acts as a negative feedback mechanism and reduces the release of the histamine mast cell. The combined effect helps to treat allergic reactions (Zuberbier et al., 2023).

From pharmacology of fexofenadine hydrochloride, the absorption, distribution, metabolism, excretion pattern, the mechanism by which it acts, toxicities and clinical trials can be known (Stielow et al., 2023). The bioavailability of the drug is 30-40%, peak plasma concentration 1-3 hours, protein binding 60-70%, the onset of action is almost 2 hours, duration of action is 12 hours and elimination half-life 13-16 hours (Sato et al., 2023).

Quality control of drugs is an operation in which drugs' physicochemical, pharmacological, pharmacokinetics, and pharmacodynamics parameters are checked periodically. It is an essential part of drug development (Glassman et al., 2019; Bodiuzzaman et al., 2017). During quality control operation, a group of tests is performed to check whether the sample drug product meets the specifications which are mentioned in the official guideline. Results obtained from the quality control test determine the fate of the product (Paul and Sun, 2017). The tests that are performed include weight-variation test**,** thickness, and diameter of tablets, friability test, hardness of tablets, disintegration of tablets, potency, and dissolution test. Determining the quality of commercial drugs and comparing them with the formulated drugs helps to identify the necessary improvements required.

The drug fexofenadine hydrochloride is manufactured and launched by different local companies in Bangladesh, comparative evaluation among manufacturers and experimental formulation has become important to determine efficiency and safety of drugs. The main purpose of this study is to evaluate the quality parameter of the commercial drug and to compare the results with formulated drug manufactured in the same pathway to check the reproducibility and integrity of the commercial tablets.

Materials and Methods

Sample collection

In the local market of Bangladesh, many manufacturers produce fexofenadine hydrochloride that has different strengths like 60 mg, 120 mg, and 180 mg. Among all strengths, the dose 120 mg is the predominant one and is most used by the consumer. Based on the assumption, a particular brand was selected of which tablets of 120 mg fexofenadine hydrochloride were taken as one sample, and 120 mg strength of fexofenadine hydrochloride was manufactured within the laboratory facility and collected as a second sample. The commercial tablets and the formulated tablets were marked as A, and B to avoid bias (Mekasha et al., 2023).

Preparation of formulated drug

To prepare fexofenadine hydrochloride in the laboratory 120 mg fexofenadine HCl was used as API, 100 mg of starch and lactose, and 50 mg of Avicel PH102 were used as diluent. 12 mg Povidone K30 was used as a binder, 15 mg Sodium starch glycolate was used as a super disintegrant, and 8 mg purified talc was used as a lubricant (Nagendrakumar et al., 2009).

Appearance of sample

According to the USP, the physical appearance of a given tablet such as color, dosage, and shape was checked and recorded in Table 1.

Table 1: Physical appearance of tablet

Color	Shape	Manufac-turing Date	Expiry Date	Type of Coating
Light Yellow	Oval	01.2022	01.2024	Film-Coated

Reagents, Apparatus, and Equipment

Reagents used in this analysis include: Distilled water, 0.001N HCL, and reference standard of fexofenadine hydrochloride. The apparatus includes a beaker, volumetric flask, conical flask, measuring cylinder,

pipette, mortar and pestle, spatula, test tube stand, thermometer, funnel, and test tube. Equipment used for the analysis includes an electronic balance, pH meter, friability tester, automatic tablet hardness tester, sonicator, digital Vernier calipers, UV-VIS spectrophotometer, tablet disintegration tester, and tablet dissolution tester.

Analytical methods

The parameters that were evaluated during the study along with the procedure given below:

Weight variation

Five commercial and five formulated tablets were taken and marked as W_1, W_2, and W_5 and weighed with analytical balance individually. After determining the average weight, the percent deviation was determined using the following formula:

$$\% \text{ Deviation} = \frac{\text{Individual wt} - \text{Average wt}}{\text{Average wt.}} \times 100$$

Diameter and thickness

Five commercial and five formulated tablets were taken and marked as D_1, D_2 .D_5 for diameter and as T_1, T_2....T_5 for thickness then diameter and thickness were measured using vernier calipers. After calculating average diameter and thickness percent deviation was determined by the following formula:

$$\%\text{Thickness} = \frac{\text{InIndividual}\dfrac{\text{Diameter}}{\text{Thickness}} - \text{Ave. Diameter/Thickness}}{\text{Average Diameter/ Thickness}}$$

Friability

Seven commercial and three formulated tablets were weighed and taken in the drum of Roche Friabilator and the drums were rotated for 4 minutes at 25 rpm. The tablets were removed followed by the dedusting of the drum. Again, tablets were weighted and noted as the final weight. %Friability was determined as follows-

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Final weight}} \times 100$$

Hardness

Three commercial and three formulated tablets were taken and placed between plates. After adjusting the scale to zero, the force was applied. Until the tablets were broken the force was increased gradually. The force that was sufficient to break tablets was noted. The procedure was repeated for the rest 5 tablets.

Disintegration time

Two commercial and two formulated tablets were used for this test. First, the disintegration apparatus was assembled. The beaker of the tester was filled with 900 ml distilled water. Temperature was fixed between 36.5-37.5ºC. The machine was started and run for a specific time. The time at which each tablet disintegrated into particles and fell into the bottom mesh was measured carefully and recorded as DT_1, DT_2, DT_3, and DT_4. By using the formula, average time was measured (Nagendrakumar et al., 2009).

Preparation of standard curve

The calibration or standard curve is made by plotting the absorbance of known concentrations on a graph. The X-axis represents concentration, while the Y-axis represents absorbance. It produces a straight line and the following equation is obtained: $Y = mx + c$. This equation may be used to determine any unknown concentration using a UV-Vis spectrophotometer and the solution's absorbance (Gholve *et al*., 2016).

In an electronic balance, 800 mg reference standard fexofenadine hydrochloride was measured and taken in a volumetric flask. Then 0.001N HCl was used to adjust the volume up to 100ml. The concentration of this solution was 8000 µg/ml which was considered as mother solution. From the mother solution 10 ml was withdrawn in another volumetric flask and to make the concentration 800 µg/ml, volume was adjusted up to 100ml using 0.001 N HCl. This was considered a stock solution. From the second volumetric flask (with a concentration of 800 µg/ml) 1 ml stock solution was taken in a test and the concentration was made to 80 µg/ml by diluting it with 9 ml media. The procedure was repeated where 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, and 10ml of stock solution were taken in 9 other test tubes and their volume was adjusted up to 10 ml using media to make concentrations of 160 µg/ ml up to 800 µg/ ml. By using a UV-spectrophotometer absorbance of 10 different working solutions was measured at 259.1 nm. Then the absorbance was plotted against concentration and a standard curve was obtained (Breier et al., 2005).

Potency: Three commercial and three formulated tablets were taken and weighed; afterward average weight was determined (Breier et al., 2005; Kaliner et al., 2003). All tablets were converted to fine particles properly by mortar and pestle and an amount of powder equivalent to the average weight of fexofenadine hydrochloride was taken which was then dissolved into the media using a sonicator or hot water bath. Using a UV-spectrophotometer, absorbance was taken of that solution at 259.1nm. The potency of tablets was measured using the following formula:

$$\% \textbf{ Potency} = \frac{\text{Drug present in a single tablet}}{\text{Strength (mg)}} \times 100$$

The drug content in a single tablet =

$$\frac{Conc.\,(mg/ml) \times dil.\,factor \times total\ vol. \times ave.\,\text{wt.}}{sample\ taken\ (mg)}$$

Dissolution test

To test the dissolution for fexofenadine hydrochloride, the following parameters were maintained according to USP (Breier et al., 2005).

- Apparatus- USP apparatus II (paddle)
- Temperature: 37±.5°C
- Time: 60 minutes
- Medium: 0.001N HCl, 900ml
- Rotation: 50 rpm
- Analysis wavelength: 259.1nm

Procedure: At first, media was prepared and it was taken into a 900 ml vessel of the apparatus for 3 tablets and temperature was maintained. Then tablets were placed in each vessel and the paddle started to run. After running the machine for a predetermined time, 10 ml of the test sample was withdrawn at a certain time (5, 10, 20, 30 45, and 60 minutes) and replaced with the medium of the same volume. After filtering the sample, the absorbance was measured by a UV-spectrophotometer at a predetermined wavelength. With the help of the standard curve release rate was determined, as a percent drug release. % Drug release was determined using the formula-

$$\%\ \text{Drug Release} = \frac{\text{Cumulative amount of release (mg)}}{\text{Strength}} \times 100$$

Results

The tablets were tested for weight variation, thickness, diameter, hardness, friability, dissolution profile, and potency. The range of test results indicates the quality and ensures optimal therapeutic effect and safety with the guidelines as well as the formulated product.

Weight variation test

The uniformity of tablets was determined by a weight variation test and recorded in Table 2. The deviation should be within specification.

Shape and diameter

The shape of fexofenadine hydrochloride was oval and the diameter of fexofenadine hydrochloride was measured and recorded as shown in Table 3 and fig. 1,

Thickness

The thickness of the tablet may differ due to differences in speed of rotation, density, and compression pressure. After measuring the thickness of tablets was recorded in table 4 and fig. 2.

Friability Test

The friability test of both commercial and formulated fexofenadine hydrochloride was measured and noted in Table 5.

Hardness

By using a digital hardness tester hardness of fexofenadine hydrochloride was measured and the force required to break the tablet was determined and listed in Table 6.

Disintegration time

The disintegration time of fexofenadine hydrochloride was measured and recorded in Table 7.

Standard curve

A standard curve was used to determine potency as well as the percent release of the drug. Different concentrations of fexofenadine hydrochloride were taken and the absorbance of different concentration were measured using a UV-spectrophotometer at 259.1 nm. Then absorbance against concentration was plotted and a standard curve was established.

Potency

Potency of tablets were recorded in the table 9.

Dissolution time

Dissolution rate of fexofenadine hydrochloride was determined and recorded in table 10, table 11, and table 12, and 13 consecutively for four tablets.

Table 2. Weight variation of Fexofenadine hydrochloride

	Sl. No.	Tablet wt. (mg)	Average weight	% Deviation
Commercial Drug	1	442	434.6	1.70%
	2	429		-1.28%
	3	432		-0.59%
	4	435		0.09%
	5	435		0.09%
Formulated Tablets	1	433	433.2	-0.04%
	2	434		0.18%
	3	434		0.18%
	4	430		-0.73%
	5	435		0.04%

Table 3. Thickness of Fexofenadine hydrochloride 120 mg tablet

Commercial tablet						**Formulated tablet**				
Sl. No.	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Main Scale (length)	12	12	12	12	12	11	10.9	11	11	11.1
Vernier Scale (length)	6	2	6	6	6	3	3.1	3	3	3
Main Scale (width)	5	4.8	5	5	5	4	4	4.1	4	4
Vernier Scale (width)	0	0	0	0	0	0	0	0	0	0
Constant	0.05									
Diameter (length, width mm)	12.3, 5	12.1, 4.8	12.3, 5	12.3, 5	12.3, 5	11.15, 4	11, 4	11.15, 4.15	11.15, 4	11.25, 4
Avg Diameter (mm)	12.26, 4.96					11.12, 4.03				
% Deviation	0.3, 8.69	-1.3, 4.34	0.3, 8.69	0.3, 8.69	0.3, 8.69	1.3, 0	0,0	1.13, 3.75	1.13. 0	1.16, 0

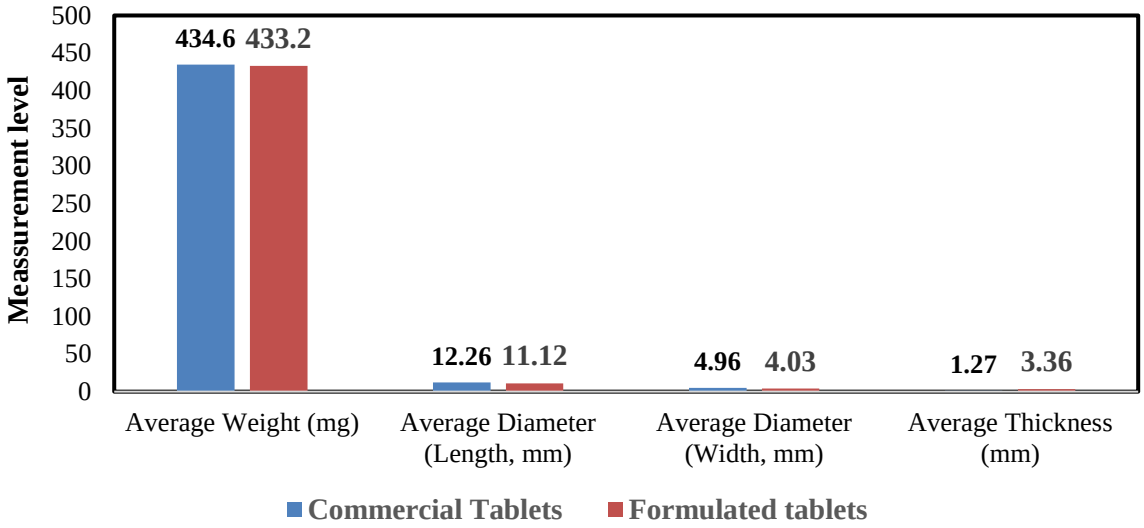

Figure 1: Average weight, average diameter and average thickness of commercial and formulated tablets.

Table 4. Thickness of Fexofenadine hydrochloride 120 mg tablet

Commercial Tablets				**Formulated Tablets**		
Sl. No.	**1**	**2**	**3**	**1**	**2**	**3**
Main scale	1	1	0.9	3	3	3
Vernier scale	6	6	6	2	1	1
Constant	0.05					
Thickness (mm)	1.3	1.3	1.2	4	3.05	3.05
Average thickness (mm)	1.27			3.36		
% Deviation	0	0.08	-7.6	19	-9.22	-9.22

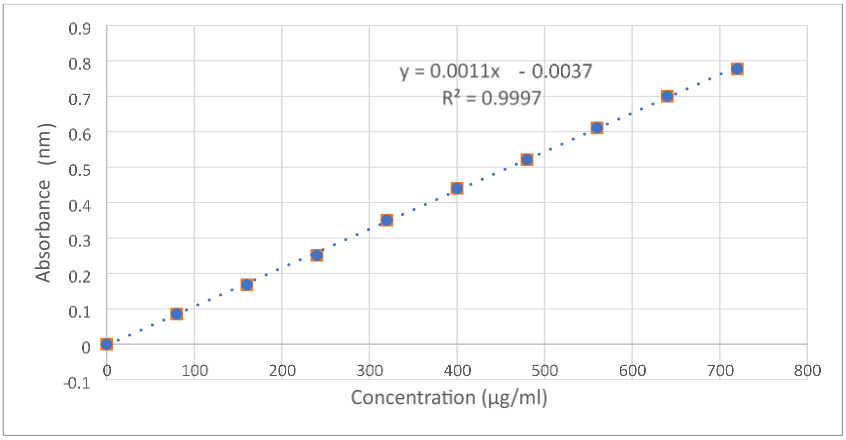

Figure 2. Standard curve of Fexofenadine hydrochloride 120 mg tablet

Table 5. Friability result of commercial and formulated fexofenadine hydrochloride tablets

	Initial weight (mg)	Final weight (mg)	% Friability
Commercial tablet (7 tablets)	3030	3030	0
Formulated tablet (3 tablets)	1550	1550	0

Table 6. Hardness of fexofenadine hydrochloride

	Tablet-1 (kp)	**Tablet-2 (kp)**	**Tablet-3 (kp)**	**Average hardness**
Commercial tablet	10.77	14.30	9.8	11.62
Formulated tablet	8	8.5	11	27.5

Table 7. Disintegration time of Fexofenadine hydrochloride

	Tablet-1 (sec)	**Tablet-2 (sec)**	**Tablet-3 (sec)**	**Average (sec)**
Commercial Tablet	69	78	101	83
Formulated Tablet	65	70	72	69

Table 8. Absorbance of reference standard of fexofenadine hydrochloride against different concentration

Sl. No.	**Concentration(µg/ml)**	**Absorbance**
1	80	0.085
2	160	0.168
3	240	0.251
4	320	0.35
5	400	0.44
6	480	0.521
7	560	0.611
8	640	0.7
9	720	0.777
10	800	0.869

Table 9. Potency of fexofenadine hydrochloride

Category of Fexofenadine HCl tablet	Absorbance	Concentration (µg/ml)	Total volume (mL)	Dilution factor	Average weight (mg)	Sample taken (mg)	Drug in a tablet (mg)	Strength (mg)	% Potency
Commercial tablet	0.42253	370	100	3	436	436	117	120	97.5
Formulated tablet	0.4244	389	100	4	433	445	119	120	99.1%

Table 10. Dissolution rate of commercial fexofenadine hydrochloride tablet-1

Time (min)	Absorbance	Conc, (µg/mL)	Conc. (mg/mL)	Amount of drug (mg/10 mL)	Amount of drug (mg/ 900 mL)	Cumulative amount released (mg)	Drug release rate (%)
5	0.035	35.18	0.03518	0.3518	31.662	31.66	26.38%
15	0.074	70.63	0.07063	0.7063	63.567	63.93	53.27%
30	0.121	113.3	0.11336	1.1336	102.024	103.08	85.90%
45	0.129	120.6	0.1206	1.1206	108.54	110.76	92.30%
60	0.137	127.9	0.1279	1.2790	115.11	118.51	98.76%

Table 11. Dissolution rate of commercial fexofenadine hydrochloride tablet-2

Time (min)	Absorbance	Conc, (µg/mL)	Conc. (mg/mL)	Amount of drug (mg/10 mL)	Amount of drug (mg/ 900 mL)	Cumulative amount released (mg)	Drug release rate (%)
5	0.045	44.27	0.04427	0.4427	39.843	39.84	33.20
15	0.081	77	0.077	0.77	69.3	69.74	58.12
30	0.11	103.36	0.10336	1.0336	93.024	94.24	78.53
45	0.123	115.18	0.11518	1.1518	103.662	105.91	88.25
60	0.134	125.18	0.12518	1,2518	112.662	116.06	96.71

Table 12. Dissolution rate of formulated fexofenadine hydrochloride tablet-1

Time (min)	Absorbance	Conc, (µg/mL)	Conc. (mg/mL)	Amount of drug (mg/10 mL)	Amount of drug (mg/ 900 mL)	Cumulative amount released (mg)	Drug release rate (%)
5	0.05	48.81	0.04881	0.4881	43.929	43.93	36.6
15	0.079	75.18	0.07518	0.7518	67.662	68.152	56.79
30	0.099	93.36	0.09336	0.9336	84.024	85.267	71.05
45	0.121	113.36	0.11336	1.1336	102.024	104.20	86.83
60	0.132	123.36	0.12336	1.2336	111.024	114.33	95.27

Table 13. Dissolution rate of formulated fexofenadine hydrochloride tablet-2

Time (min)	Absorbance	Conc, (µg/mL)	Conc. (mg/mL)	Amount of drug (mg/10 mL)	Amount of drug (mg/ 900 mL)	Cumulative amount released (mg)	Drug release rate (%)
5	0.048	46.9	0.0469	0.469	42.21	43.1	35.9
15	0.08	77.3	0.0773	0.773	69.57	69.27	57.72
30	0.124	95	0.095	0.95	85.5	85.267	71.05
45	0.129	119.36	0.11936	1.1936	107.42	88.87	74.05
60	0.135	121.36	0.12136	1.2136	110.43	111.143	92.6

Discussion

In order to establish quality and to evaluate whether the tablets satisfy USP guidelines, a comparative quality control study is required. The comparative study is performed to assess the efficiency of commercially available fexofenadine hydrochloride marketed by local manufacturers by detecting quality control tests. Pharmaceutical equivalence of products is measured by checking the uniformity in weight, thickness and diameter among tablets. These parameters also ensure uniformity in batch to-batch production (Afroz et al., 2022).

The result obtained from the test, average weight of commercial tablets is 434.6 mg, and of the formulated tablet is 433.2mg. Tablets may have slightly different weights if the excipients are unequally distributed or the granules of poor flow properties. Poor mixing, Insufficient lubrication, punch length difference, and low or high speed of production machine can also contribute to the uneven weight of tablets (Perrault et al., 2011). To reduce deviation from
standard weight, an adequate amount of glidant should be added to ensure good flow property of granules and the size of granules should be made more uniform (Zegzulka et al., 2016). According to the guideline provided in USP, ±7.5% deviation is allowed if the weight of the tablet ranged from 130 mg to less than 324mg [Li et al., 2021]. So, from the aspect of uniformity in weight, both the commercial tablet and formulated tablet are accepted. In the case of tablet thickness and diameter variation of about ±5% is acceptable from the standard value according to USP (Gade et al., 2022). In this study, the average thickness and diameter for the commercial tablet was 1.2mm and 12.6 (length), 4.6 (width) mm, respectively, and for formulated tablet was 3.36 mm, and 11 (length), 4(width) mm.

The disintegration time of the tablet is associated with the hardness of the tablet. If an excess amount of binder is added to the tablet it contributes to unusual hardness which leads to prolonged disintegration of tablets. On the contrary, if the hardness of the tablet is insufficient, the tablets become fragile and may break during packaging, distribution, handling, and transporting (Gade et al., 2022). So, it is necessary for a tablet to have sufficient hardness which was present in the tablet used for the study. The hardness of three commercial tablets was 10.77kp, 14.30kp and 9.8 respectively with an average hardness of 11.62kp.and for formulated tablets was 8kp, 8.5 kp, and 11 kp with an average hardness of 27.5kp. According to USP, the hardness of film-coated tablets should be 9-11kp (Kassahun and Bezabih, 2022).

The dissolution rate of the tablet in solution is affected by disintegration time. Absorption occurs followed by disintegration so it also affects the absorption rate. The type and amount of binder, disintegrants, and hardness of the tablet all together affect the disintegration rate of the tablet. From the study disintegration time of three commercial tablets was found 69 seconds, 78 seconds, and 101 seconds respectively, and of formulated tablets 65 seconds, 70 seconds, and 72 seconds. According to USP, the disintegration time for film-coated tablets should not exceed 30

minutes (Eedara et al., 2021). So, the batch was maintained within the specification.

Friability is a process by which the mechanical strength of tablets is determined. The mechanical strength of the tablet should be such that it can withstand abrasion, vibration, and shock while handling and transporting. Tablets tend to lose particles if subjected to vibration or abrasion and this tendency is measured by the friability test. The stability of the tablet is influenced by the granulation process and compression pressure. High-quality tablets should have a friability of less than 1%. The friability of the collected sample is 0% which indicates adequate mechanical strength of the tablets (Osei-Yeboah and Sun, 2015).

The bioavailability of the drug is largely influenced by the dissolution rate of the tablet. It is also important for sufficient absorption The release rate of the drug at 60 minutes should be at least 75% as guided by USP (Eedara et al., 2021). From the study, the rate of release of drug from two commercial tablets was obtained at 98.76%, and 96.71%, and for two formulated tablets was 95.27% and 92.6% respectively at 60 minutes. As the release rate of these tablets remained within the specified range, the batch conforms to the parameters and the desired therapeutic effect can be achieved.

The intensity of the pharmacological effect of a tablet can be confirmed by the tablet's potency. If the potency of a tablet remains higher than the range, it indicates the tablet may produce toxicity. Also, lower potency indicates poor therapeutic efficiency of a tablet (Meltzer et al., 2021). So to produce the desired effect the tablet should have sufficient potency which ranges from 95% to 105%. The potency of the commercial tablet was 97.5% and that of the formulated tablet was 99.1% which lies in the acceptable range confirming the quality of the tablet batch.

Conclusion

According to the analysis, this brand complied with the USP guidelines. From the result, it can be seen that the commercial tablets possess almost similar qc parameters as the formulated drug confirming the reproducibility of the product. From this study, it can be said that the commercial tablet batch of fexofenadine hydrochloride possesses satisfactory quality and high efficiency. As a result, it can be concluded that Bangladeshi pharmaceutical companies are reliable in manufacturing high-quality reproducible products. Before launching a product, it is important to assess the different quality parameters of the tablet to ensure the efficacy of the product. To raise public awareness about the integrity of locally manufactured products these kinds of analyses should be performed more frequently.

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Conflicts of Interest

The authors declare no conflict of interest for financial or intellectual or others.

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