Comparative Evaluation of Quality Control Parameters between Commercially Available and Formulated Tablets of Fexofenadine Hydrochloride 120 mg

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Abstract

Background: Fexofenadine hydrochloride is a second-generation antihistamine that works by blocking H2 receptor and primarily indicated for allergic rhinitis. To satisfy the desired pharmacological effect it is important for a drug to comply all the specification with the guideline. This study has been conducted to evaluate the quality parameters of commercial drug and establish a comparative screening of commercial drug with the formulated one. **Methods:** Fexofenadine HCl was formulated in the laboratory setup and one particular brand was selected and compared with formulated drug. Quality parameter was checked by performing potency and dissolution test, weight variation test, thickness hardness-diameter determination, disintegration time detection and friability test. **Results:** The test result has shown that formulated dug has similar potency than the commercial drug with the commercial drug achieving the 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. **Conclusion:** 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 desired pharmacological effect.

Keywords: Commercial Drug, Formulated Drug, Fexofenadine hydrochloride, Quality control parameters.

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 as allergic rhinitis, runny nose, sneezing etc [Turkmen *et al*., 2018]. The drug is popular due to its avoidance of adverse reaction associated with central nervous system because of its unavailability to cross blood-brain-barrier. These drugs have more specificity and selectivity toward receptors compared to the first generation antihistamines [Slater et al., 2012]. The drug mimics the structure of histamine and bind to histamine receptor [Parisi et al., 2020] . This prevents the histamine to produce their action as they cannot bind to it. The blocking of receptor also acts as negative feedback mechanism and

reduce the release of histamine mast cell. The combined effect helps to treat allergic reaction [Church and Church, 2013].

From pharmacology of fexofenadine hydrochloride, the absorption, distribution, metabolism, excretion pattern, mechanism by which it acts, toxicities and clinical trials can be known. The bioavailability of the drug is 30-40%, peak plasma concentration 1-3 hours, protein binding 60-70%, onset of actin is almost 2 hours, duration of action is 12 hours and elimination half-life 13-16 hour [Ortonne, 2012].

Quality control of drugs is an operation in which drugs physicochemical, pharmacological, pharmacokinetics and pharmacodynamics parameter are checked periodically. It is an essential part of a drug development [Raka et al., 2017]. During quality control operation, a group of tests are performed to check whether the sample drug product meet the specification which are mentioned in official guideline. Result obtained from the quality control test determine the fate of the product [Paul and Sun, 2017]. The test that are performed include weight-variation test**,** thickness and diameter of tablets, friability test, hardness of tablets, disintegration of tablets, potency, dissolution test. Determining the quality of commercial drug and comparing with the formulated drug helps to identify the necessary improvement required.

The drug fexofenadine hydrochloride is manufactured and launched by different local companies in Bangladesh, comparative evaluation among manufacturer 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.

Methods and Materials

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

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 binder, 15 mg Sodium starch glycolate was used as super disintegrant and 8 mg purified talc was used as lubricant.

Appearance of Sample: According to USP, physical appearance of a given tablet such as color, dosage, shape was checked and recorded in table 1:

Table 1: Physical Appearance of Tablet

Color	**Shape**	**Manufacturing Date**	**Expiry Date**	**Type of Coating**
Light Yellow	Oval	01.2022	01.2024	Film-Coated

Reagents, Apparatus and Equipment: Reagents used in this analysis in include: Distilled water, 0.001N HCL, reference standard of fexofenadine hydrochloride. Apparatus includes: beaker, volumetric flask, conical flask, measuring cylinder, pipette, mortar and pestle, spatula, test tube stand, thermometer, funnel, test tube. Equipment used for the analysis include: electronic balance, pH meter, friability tester, automatic tablet hardness tester, sonicator, digital Vernier calipers, UV-VIS spectrophotometer, tablet disintegration tester, tablet dissolution tester.

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

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

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

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

$$\% \text{ Deviation} = \frac{\text{InIndividual Diameter/Thickness} - \text{Average Diameter/Thickness}}{\text{Average Diameter/ Thickness}}$$

Friability: Seven commercial and three formulated tablets were weighed and taken in drum of Roche Friabilator and the drums were rotated for 4 minutes at 25 rpm.The tablets were removed followed by dedusting of drum. Again, tablets were weighted and noted as 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 were noted. The procedure was repeated for 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 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 gets disintegrated into particles and fall into bottom mesh were measured carefully and recorded as DT_1, DT_2, DT_3, DT_4. By using formula, average time was measured.

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 concentration 800 µg/ml, volume was adjusted up to 100ml using 0.001 N HCl. This was considered as stock solution. From the second volumetric flask (with concentration 800 µg/ml) 1 ml stock solution was taken in a testube and concentration was made 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 were adjusted up to 10 ml using media to make concentrations of 160 µg/ ml up to 800 µg/ ml. By using UV-spectrophotometer absorbance of 10 different working solutions were measured at 259.1 nm. Then the absorbance was plotted against concentration and standard curve was obtained.

Potency: Three commercial and three formulated tablets were taken and weighted, afterwards average weight was determined. All tablets were converted to fine particles properly by mortar and pestle and amount of powder equivalent to average weight of fexofenadine hydrochloride was taken which was then dissolved in to the media using sonicator or hot water bath. Using UV-spectrophotometer, absorbance was taken of that solution at 259.1nm. Potency of tablets were measured using following formula:

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

Drug in a single tablet =

$$\frac{concentration\ (mg/ml) \times dilution\ factor \times total\ volume \times average\ weight.}{sample\ taken\ (mg)}$$

Dissolution Test: To test the dissolution for fexofenadine hydrochloride, following parameters were maintained according to USP.

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

Weight Variation Test

Uniformity of tablets were determined by weight variation test and recorded in table 2. The deviation should be within specification.

Table 2: Weight Variation Test of Fexofenadine Hydrochloride

	Sl. No.	**Wt of tablet (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%
	1	433	433.2	-0.04%

Formulated Tablets	2	434		0.18%
	3	434		0.18%
	4	430		-0.73%
	5	435		0.04%

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.

	Sl. No	**Main Scale(length)**	**Vernier Scale(length)**	**Main Scale(width)**	**Vernier Scale(width)**	**Constant**	**Diameter (length,width mm)**	**Avg Diameter (mm)**	**% Deviation**
Commercial Tablets	1	12	6	5	0		12.3,5	12.26, 4.6	0.3, 8.69
	2	12	2	4.8	0		12.1,4.8		-1.3 4.34
	3	12	6	5	0		12.3,5		0.3, 8.69
	4	12	6	5	0		12.3,5		0.3. 8.69
	5	12	6	5	0		12.3,5		0.3. 869
	1	11	3	4	0	0.05	11.15, 4		1.3, 0
	2	10.9	3.1	4	0		11,4.		0,0
	3	11	3	4.1	0		11.15, 4.15		1.13,3.75
	4	11	3	4	0		11.15,4		1.13,0

Formulated Drugs	5	11.1	3	4	0		11.25,4	11,4	1.16,0

Thickness: Thickness of tablet may differ due to difference in speed of rotation, density, compression pressure. After measuring the thickness of tablets was recorded in table 4.

Table 4: Thickness of Fexofenadine Hydrochloride 120 mg Tablet

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

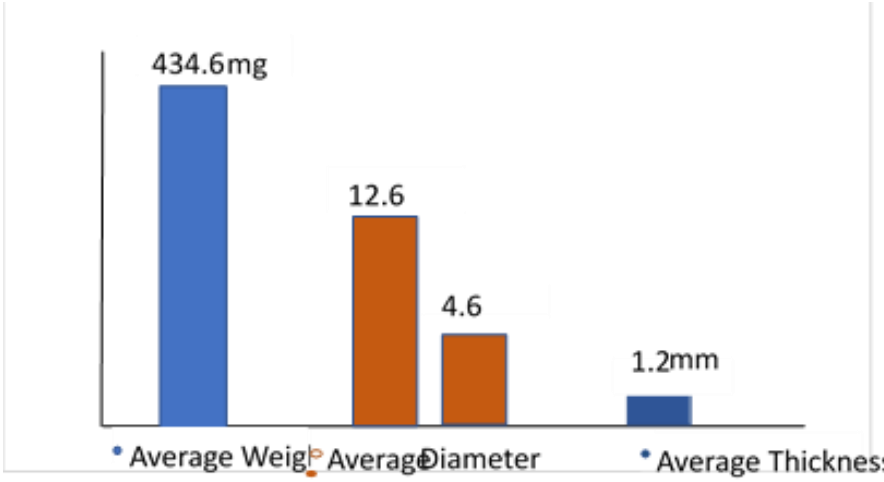

Figure 1: Average Weight, Average Diameter and Average Thickness of Commercial Tablet

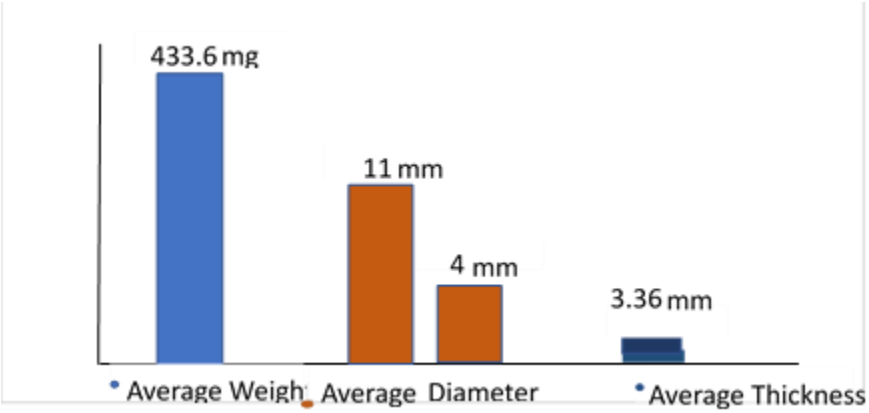

Figure 2: Average Weight, Average Diameter and Average Thickness of Formulated Tablet

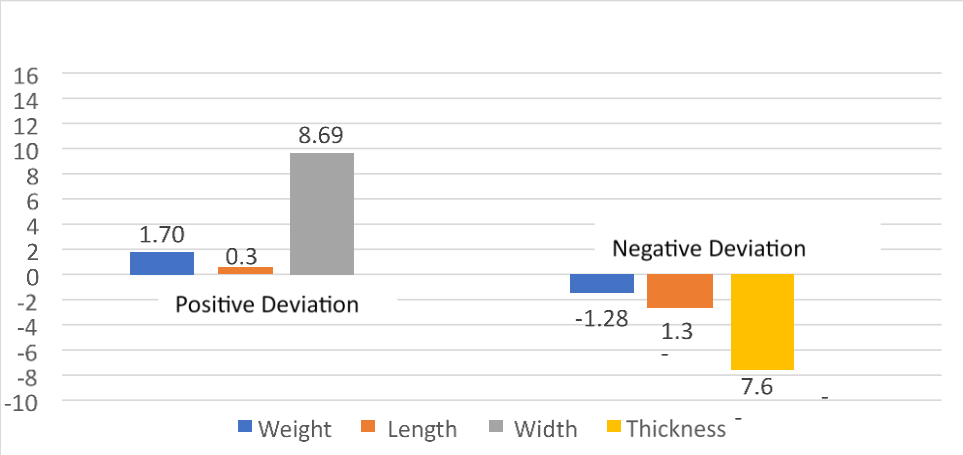

Figure 3: Highest Positive and Negative Percent of Deviation of Weight, Diameter

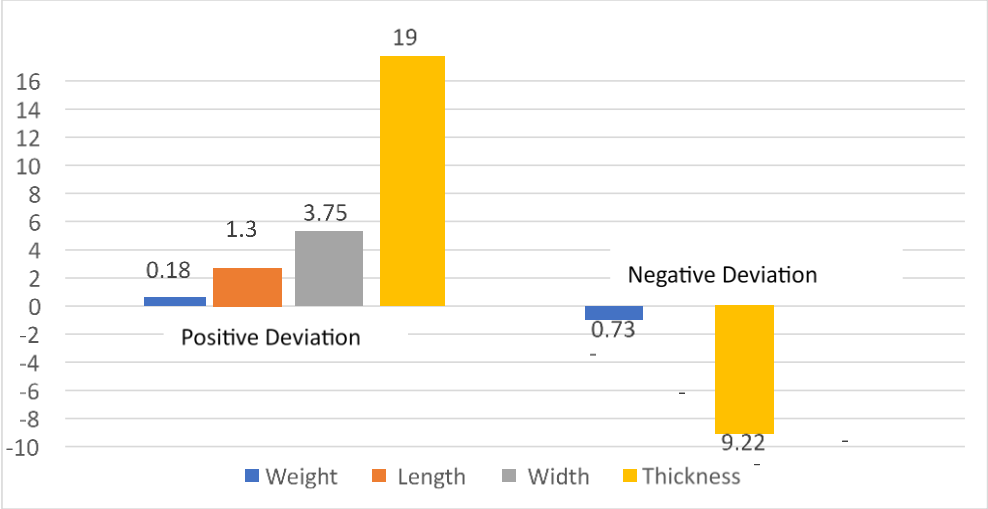

Figure 4: Highest Positive and Negative Percent of Deviation of Weight, Diameter and Thickness of Formulated Tablets

Friability Test: Friability test of both commercial and formulated fexofenadine hydrochloride was measured and noted in table 5

Table 5: Friability result of Commercial and Formulated Tablets

	Initial Weight (mg)	**Final Weight (mg)**	**%Friability**
Commercial Tablets (7 tablets)	3030	3030	0
Formulated Tablets (3 tabletss)	1550	1550	0

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

Table 6: Hardness of Fexofenadine Hydrochloride

	Tablet-1(kp)	**Tablet-2(kp)**	**Tablet-3(kp)**	**Avg hardness**
Commercial Tabet	10.77	14.30	9.8	11.62

Formulated Tablet	8	8.5	11	27.5

Disintegration Time: Disintegration time of fexofenadine hydrochloride was measured and recorded in the table 7.

Table 7: Disintegration Time of Fexofenadine Hydrochloride

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

Standard Curve:

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

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

The values from table 8 was plotted in the graph and the standard curve obtained is attached in the figure

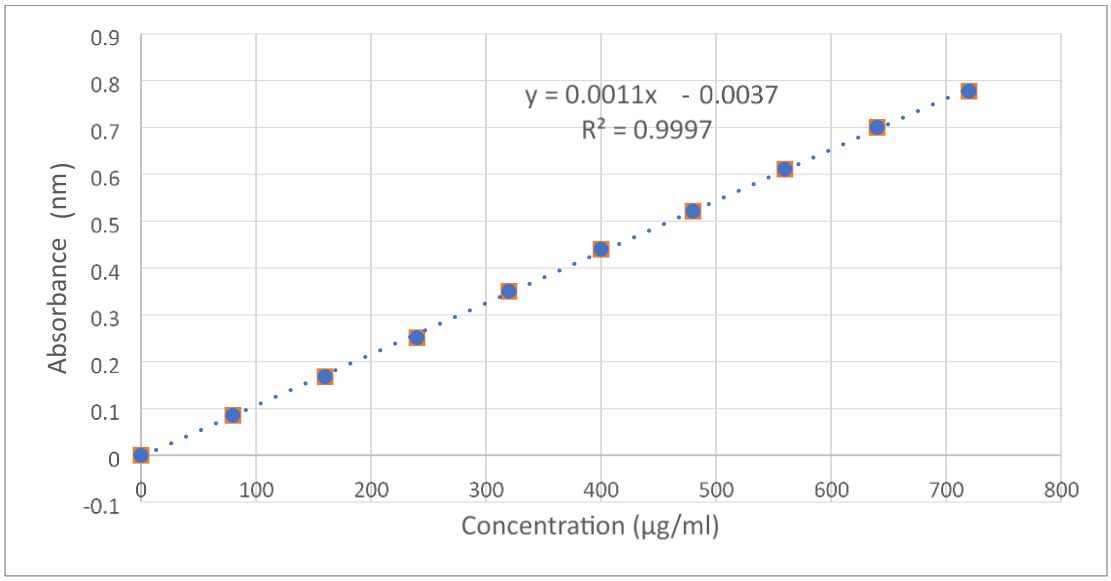

Figure 5: Standard Curve of Fexofenadine Hydrochloride 120 mg Tablet

Potency : Potency of tablets were recorded in the table 9.

Table 9: Potency of Fexofenadine Hydrochloride

	Abs	**Conc(µg/ml)**	**Total Vol.(ml)**	**Dilution Factor**	**Avg Wt (mg)**	**Sample Taken (mg)**	**Drug in a Tablet (mg)**	**Strength (mg)**	**%Potency**
Commecial Tablet	0.4253	370	100	3	436	436	117	120	97.5
Formulated Tablet	0.4244	389	100	4	433	445	119	120	99.1%

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

Table 10: Dissolution Rate of Commercial Fexofenadine Hydrochloride Tablet-1

Time (min)	**Abs**	**µg/ml**	**mg/ml**	**mg/10 ml**	**mg/900ml**	**Cumulative Amount Release**	**%Release**
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)	**Abs**	**µg/ml**	**mg/ml**	**mg/10ml**	**mg/900ml**	**Cumulative Amount Release**	**%Release**
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)	**Abs**	**µg/ml**	**mg/ml**	**mg/10ml**	**mg/900ml**	**Cumulative Amount**	**%Release**

						Release	
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)	**Abs**	**µg/ml**	**mg/ml**	**mg/10ml**	**mg/900ml**	**Cumulative Amount Release**	**%Release**
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 guideline, 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 among batch to-batch production.

The result obtained from test, average weight of commercial tablets is 434.6 mg and of formulated tablet is 433.2mg. Tablets may have slightly different weight if the excipients are unequally distributed or due to the granules of poor flow property. Poor mixing, Insufficient lubrication, punch length difference, low or high speed of production machine can also contribute to uneven

weight of tablets. To reduce deviation from standard weight, adequate amount of glidant should be added to ensure good flow property of granules and the size of granules should be made more uniform. According to the guideline provided in USP, ±7.5% deviation is allowed if the weight of 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 case of tablet thickness and diameter variation of about ±5% is acceptable from the standard value according to USP [Ahmed *et al.*,2013]. In this study, the average thickness and diameter for commercial tablet was 1.2mm and 12.6(length),4.6(width)mm respectively and for formulated tablet was 3.36mm and 11(length),4(width)mm.

The disintegration time of tablet is associated with the hardness of tablet. If excess amount of binder is added to the tablet it contributes to unusual hardness which leads to prolong disintegration of tablets. On contrary, if hardness of tablet is insufficient, the tablets become fragile and may break during packaging, distribution, handling and transporting [Ahmed *et al.,*2013]. So, it is necessary for a tablet to has sufficient hardness which was present in the tablet used for the study. The hardness of three commercial tablets were 10.77kp, 14.30kp and 9.8 respectively with average hardness of 11.62kp.and for formulated tablets were 8kp, 8.5 kp and 11 kp with average hardness of 27.5kp. According to USP, the hardness of film-coated tablet should be 9-11kp.

Dissolution rate of 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 tablet all together affect the disintegration rate of tablet. From the study disintegration time of three commercial tablets were found 69 seconds, 78 seconds and 101 seconds respectively and of formulated tablets were 65 seconds, 70 seconds and 72 seconds. According to USP, the disintegration time for film-coated tablet should not exceed 30 minutes [Eedara *et al*., 2021]. So, the batch were maintained within the specification.

Friability is a process by which mechanical strength of tablets are determined. The mechanical strength of tablet should be such that it should withstand abrasion, vibration and shock while handling, transporting. Tablets tend to loss particles if subjected to vibration or abrasion and this tendency is measured by friability test. Friability of tablet is influenced by granulation process, compression pressure. High-quality tablet should have friability less than 1% [Ahmed *et al.*,2013]. Friability of collected sample is 0% which indicates adequate mechanical strength of tablets.

Bioavailability of drug is largely influenced by dissolution rate of tablet. It is also important for sufficient absorption The release rate of 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 were obtained 98.76%, 96.71% and for two formulated tablets were 95.27% and 92.6% respectively at 60 minutes. As the release rate of these tablets remained within specified range, the batch conform to the parameters and desired therapeutic effect can be achieved.

The intensity of 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 desired effect the tablet should have sufficient potency which ranges from 95% to 105%. The potency of the commercial tablet was 97.5% and of 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. The drug was formulated in laboratory and subjected to qc tests and considered as standard with which the quality control results of commercial tablets was compared. From the result it can be seen that the commercial tablets possess almost similar qc parameter as the formulated drug confirming the reproducibility of the product. From the study, it can be said that the tablet batch of fexofenadine hydrochloride possess 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 tablet to ensure the efficacy of the product. From the study it can be emphasized that the tablet batch has adequate quality. To raise public awareness about the integrity of locally manufactured products these kinds of analysis should be performed more frequently.

Acknowledgement

The authors are grateful to, Sayma khaan, student of department of pharmacy, University of Asia Pacific for providing necessary formulated tablets. We would also like to thank to Department of Pharmacy, University of Asia Pacific for the technical support of study.

Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

Funding Information

No funding

Reference

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Figure legends:

Figure 1: Average Weight, Average Diameter and Average Thickness of Commercial Tablet

Figure 2: Average Weight, Average Diameter and Average Thickness of Formulated Tablet

Figure 3: Highest Positive and Negative Percent of Deviation of Weight, Diameter

Figure 4: Highest Positive and Negative Percent of Deviation of Weight, Diameter and Thickness of Formulated Tablets

Figure 5: Standard Curve of Fexofenadine Hydrochloride 120 mg Tablet