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Quality control assessment of different selective brands of famotidine and cimetidine

Uzma Yasmeen *, Ghulam Razaque, Noman Ul Haq, Nisar Ahmed Shahwani, Muhammad Arsalan, Ghulam Mustafa shahwani, Rasheed Ahmed, Abdul Ghaffar, Naila Masood and Abdullah

Faculty of Pharmacy and Health Sciences, University of Balochistan, Quetta, Pakistan.

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Abstract

Famotidine reduces the production of stomach acid. The pharmacological action of this drug is to treat the acid production which are related to gastrointestinal conditions. As famotidine is accessible in both medicine and (OTC) over the counter drug it is used in the GERD gastro -esophageal for the gastric and duodenal ulcer both. Cimetidine is a H2 receptor drug used to treat the stomach diseases like peptic ulcer while in other countries there is exemption to the POM class where for the momentary symptomatic help of acid reflux, hyperacidity, and dyspepsia. The main purpose of this research was to check the physical and chemical quality control studies of different brands of cimetidine and famotidine brands which are available in the market of Quetta Baluchistan city and mostly prescribed by different prescribers. Different brands were selected of cimetidine were Tagamet, Comet, Cimepha and Famotidine brands were Bessfam, Famot, H2F, Zepsin and Ulfam. The Physiochemical studies of selected brands were analyzed which includes Friability, Weight variation, Thickness, Hardness, Disintegration, Dissolution and all brands were compared with each other. The physiochemical properties results of selected different market brand cimetidine and Famotidine when compare each brand with each other these indicated that all selected brands were according to the limits which were in acceptable range and compliance the qualifications of BP and USP. It is concluded that this type of research may be conducted to check the different brands of different formulations not only tablet for all the different formulations may be examined accordingly and compared with the specification. This type research may will give accurate information to the prescriber drug regulatory authorities as well as to manufacturers for best formulations available in the market and the results which are not according to the limits may be pointed out and inform to the regulatory authorities.

Keywords: Famotidine; Cimetidine; Quality Control; BP; USP

1. Introduction

Famotidine reduces the production of stomach acid. The pharmacological action of this drug is to treat the acid production which are related to gastrointestinal conditions. (1). As famotidine is accessible in both medicine and (OTC) over the counter drug it is used in the GERD gastro-esophageal for the gastric and duodenal ulcer both (2) Famotidine is additionally for the over counter treatment approved counteractive action of acid reflux by FDA because of gastro-esophageal reflux in adults and pediatrics. (3) Famotidine is used to rotten mark for lessening gastrointestinal dangers of non-steroidal anti-inflammatory drug. (4) It is additionally used to treat the urticarial and severe-headache, counteractive action of pressure ulcer and in basically sick symptomatic patients which also help in the Gastritis (3).

Famotidine is .the (OTC) drug. It is accessible with professionally prescribed medications for the treatment of gastro-esophageal reflux illness, gastric ulcer, duodenal ulcer in teenagers, and grown-ups with extra signs for the treatment of cutting edge hyper secretory conditions in grown-ups. Famotidine has additionally been affirmed by the FDA for over-the-counter PC and cardiovascular capacity for thought of gastro-esophageal reflux in grown-ups and pediatric

* Corresponding author: Uzma Yasmeen
Faculty of Pharmacy and Health Sciences, University of Balochistan, Quetta, Pakistan.

examinations. Famotidine is used for marking to reduce the intestinal risks of NSAIDs. (5). Cimetidine is a H2 receptor drug used to treat the stomach diseases like peptic ulcer while into other countries there is exemption to the POM class where for the momentary symptomatic help of acid reflux, hyperacidity, and dyspepsia (6). Cimetidine was affirmed 1976 in UK and in erlear1979 it was perceived in the USA by FDA for various cures of abdomen (7).

GMPs is the part Quality Assurance department according to which products are manufactured produced according to a standard. A drug item should be made as per given rules so as wanted standard nature of an item or helpful gadget can be accomplished. (8). Quality Assurance is wide thought from which all boundaries are joins that basically begins managing each rough fixing the things and besides the official's stress with the creation, and creation, its organization and assessment technique. It similarly associated in pre-definition stage to meet and check all of the judgments and necessities while in the midst of thing headway steps. For the most part, 2 principles that also applied in the quality attestation, for instance, "fit for reason" some drug organizations' thing should remain legitimate and proposed uses and "right first time" bungles should stand cleared out solidly. For improve quality affirmation structure simply finishing the heads of Good assembling rehearses furthermore expect a fundamental activity close recuperate the quality (9). Quality control is a process utilized to guarantee the degree of value in item or services. The fundamental motivation behind the quality control to guarantee that the items, meet process fulfill the requirements of the standards (10).

2. Material and methods

2.1. Material

Available brands of cimetidine and famotidine tablets were collected from the Market of the Quetta City which are mostly prescribed by the prescribers.

Table 1 Different Brand names and manufacturers of Cimetidine

Brand No.	Brand Name	Manufacturer
1	Tagamet	GSK KCH
2	Comet	FEROZSONS Laboratories Nowshera
3	Cimepha	EPHARM Laboratories KCH

Table 2 Different Brand names and manufacturers of Famotidine

S. No	Brand name	Manufacturer
1	Bessfam	HIGH-Q Pharmaceutical
2	Famot	SHAIGAN Pharmaceutics
3	H2F	Feroz sons Laboratories
4	Zepsin	Cirin Hatar
5	Ulfam	Focus & Rolls Islamabad

2.2. Chemicals and Glassware used

Conical Flasks (Pyrex, England), Pipettes 10ml, 50ml (Pyrex, England), Volumetric Flasks 50 ml, 100 ml, 1000 ml (Pyrex, England), Beakers 10 ml,50 ml ,100 ml (Pyrex, England), Filter paper (Watt man), Magnetic stirrer, Glass stirrer, Famotidine, Cimetidine.

2.3. Equipment's

Hardness tester (Pharma test, Germany), Disintegration Apparatus (Shimadzu), Dissolution Apparatus (Pharma test, Germany), Single beam Spectrophotometer (CECIL, England), pH meter (model No. Ino lab Level-1 Pyrex England), Vernier caliper, Electronic Balance.

2.4. Methods

2.4.1. Weight Variation Test

Weighed the 20 tablets accurately taken randomly determined the average weight. Weighed all the individual tablets of each brand by the help of electronic balance and results were calculated according to the specifications. To be acceptable, not more than two of the individual loads deviated from the normal load by more than the % deviation and not strayed by more than double that rate.

2.4.2. Thickness Test

Thickness of tablets were determined in mm to use Hardness tester (Model No.PTB-311E Pharma test Germany) and data was statistically analyzed. The Pharmacopeia permits some slight deviation usually ±5 % from the normal diameter (11).

2.4.3. Hardness Test

This test tablets are usually expressed as the load required to break tablets at its edges. Hardness is thus sometimes termed as the tablet crushing strength. For to know the hardness for which this model hardness tester was used (Model No.PTB-311E Pharma test Germany). The tablet was kept in between two jaws of the hardness tester and force is applied and break is recorded (12).

2.4.4. Disintegration Test

The disintegration test was applied on the tablets using the disintegration apparatus (Model No. PTZ Germany) 6 tablets were placed in each of 6 tubes of basket, added a disk to each tube and operated the apparatus using distilled water as immersion fluid, maintained at 37 °C ± 2. The time was observed until tablet has been disintegrated completely. It was reported in (13) that all the tablets must disintegrate completely if 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. Out of 18 tablets 16 should disintegrate within 30 minutes (film coated) and 15 minutes for (uncoated tablets) (13).

2.4.5. Dissolution Test

The vessel is halfway submerged in a reasonable water shower of any advantageous size or put in a warming chamber. The water shower or warming coat licenses holding the temperature inside the vessel at 37±0.5°C during the test and keeping the shower liquid in steady, smooth movement. No piece of the get together, remembering the climate for which the gathering is set, contributes huge movement, tumult, or vibration past that due to the easily turning blending component. The vessel is barrel shaped, with the hemispherical base, for a typical limit of 1liter, the tallness is 160 mm-210 mm and its inside distance across is 98 mm-106 mm; for an ordinary limit of 2 liters, the stature is 280 mm-300 mm and its inside measurement is 98 mm-106 mm; and for ordinary limit of 4 liters; the stature is 2 mm-300 mm and its width is 145 mm-155 mm (13).The shaft is situated so its hub is not more than 2 mm anytime from the vertical hub of the vessel and turns easily without huge wobble. The distance of 25±2mm between the edge and inside lower part of the vessel is kept up during the test. A speed managing gadget is utilized that permits the shaft pivoting pace to be chosen and kept up at the rate indicated with in ±4 %, (13). Medium was set up by utilizing 900 ml of the phosphate support dissolving 2.62 gm of monobasic sodium Phosphate and 11.50 gms of anhydrous di-fundamental sodium phosphate in distil water to make 1000 ml, and changing the pH (13).

3. Results and discussion

Table 3 Thickness test of Cimetidine Brands in mm

S.NO	Tagamet mm	Cimet mm	Cimepha mm
1	6.25	5.43	6.13
2	6.27	5.44	6.22
3	6.36	5.47	6.20
4	6.36	5.46	6.07
5	6.31	5.46	6.18
6	6.32	5.46	6.07
7	6.35	5.40	6.10

8	6.44	5.47	6.14
9	6.37	5.46	6.07
10	6.33	5.51	6.16

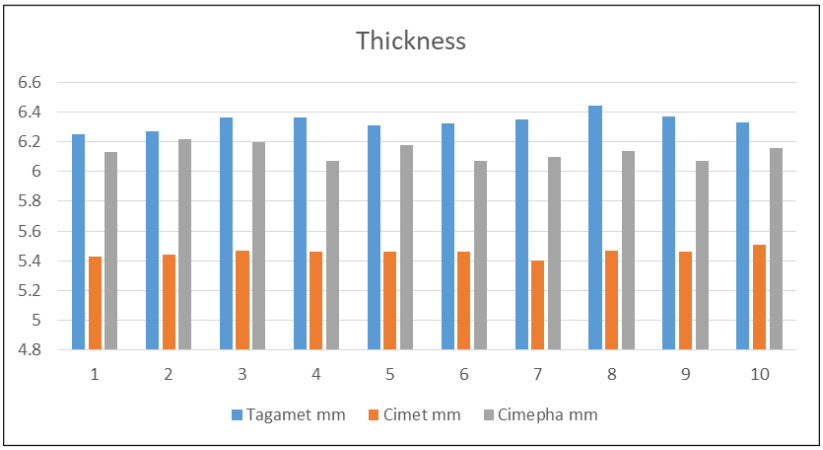

Figure 1 Thickness test of Cimetidine Brands in mm

Thickness of Tagamet, Cimet, Cimepha were checked by digital Vernier caliper. The average weight of Tagamet and Cimepha were slightly higher than Cimet.

Table 4 Weight variation test of Cimetidine Brands in gm

S NO	Tagamet gm	Cimet gm	Cimepha gm
1	0.5684	0.515	0.538
2	0.5684	0.517	0.519
3	0.5683	0.512	0.513
4	0.5678	0.504	0.511
5	0.5659	0.511	0.510
6	0.5659	0.511	0.551
7	0.5700	0.515	0.499
8	0.5701	0.515	0.498
9	0.5947	0.519	0.511
10	0.5946	0.520	0.558
11	0.5729	0.516	0.536
12	0.5729	0.514	0.520
13	0.5928	0.514	0.511
14	0.5954	0.506	0.500
15	0.5954	0.504	0.518
16	0.5952	0.509	0.537
17	0.5952	0.510	0.551
18	0.5765	0.515	0.556
19	0.5706	0.517	0.538
20	0.5848	0.517	0.518

All brands weight were checked and results were drawn, these brands were within the specified limits. However only minute variances were observed. Tabulated results showed weight variance within the range of ±5% which is according to the specification of USP.

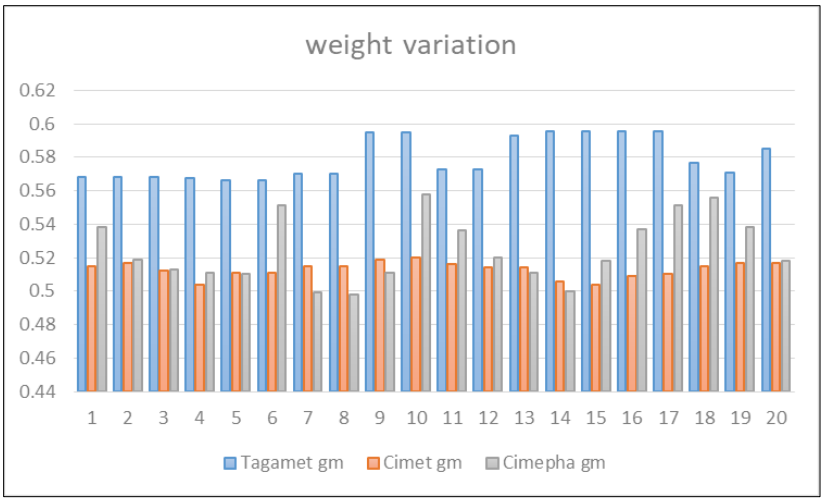

Figure 2 Weight variation test of Cimetidine Brands in gm

Table 5 Hardness test of Cimetidine Brands in Kg

S.NO	Tagamet (Kg)	Cimet (Kg)	Cimepha (Kg)
1	07.7	13.2	13.2
2	07.7	14.5	14.5
3	08.8	14.2	14.2
4	09.5	13.2	13.2
5	09.3	14.2	14.2
6	07.3	11.8	11.8
7	07.3	14.6	14.6
8	08.1	13.9	13.9
9	07.3	13.8	13.8
10	07.71	14.3	14.3

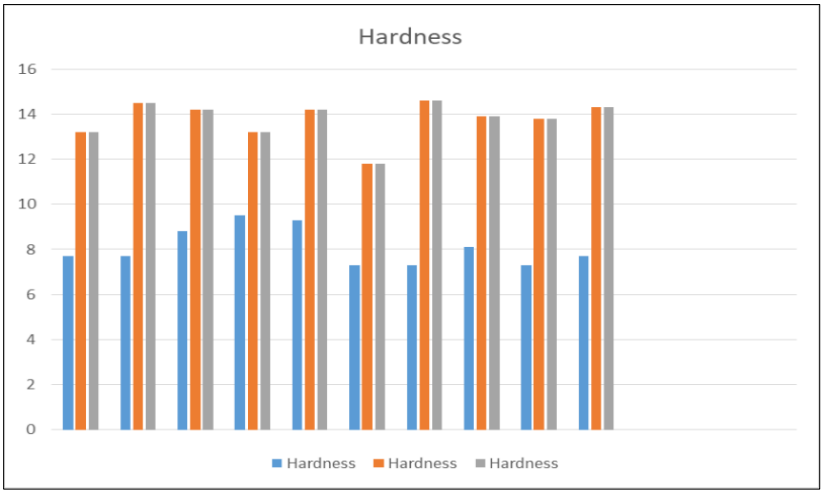

Figure 3 Hardness test of Cimetidine Brands in Kg

Hardness of all brands were checked in like manner, contrasted with one another and arranged. Result noted and found minute distinction among these tablets strayed from the principles determined in standard USP ±5%.

Table 6 Friability test of Cimetidine Brands

Weight	Tagamet	Cimepha	Cimet
Weight before friability	2.82	5.33	5.10
Weight after friability	2.81	5.32	5.09
Variance	0.01	0.01	0.01
%age	0.35	0.18	0.196

The outcomes were incorporated as every one of these brands were checked their Friability and contrasted and one another. The results of Friability were inside the cutoff points referenced in determinations of USP, for example tablets should not misfortune 0.5% to 1% of their underlying weight.

Table 7 Disintegration test of Cimetidine Brands

S. No	Brands Name	Results
1	Tagamet	1 to 2 min
2	Cimet	Within 4 min
3	Cimepha	Within 3 min

Disintegration of all various brands were checked appropriately, analyzed, and classified. It was tracked down that every one of the tablets were inside the details as indicated by the USP for example underneath than 10 minutes it implies drug organizations are observing the principles of USP.

Table 8 Dissolution test of Cimetidine Brands

Tagamet	Cimet	Cimepha
103.603	101.100	103.107

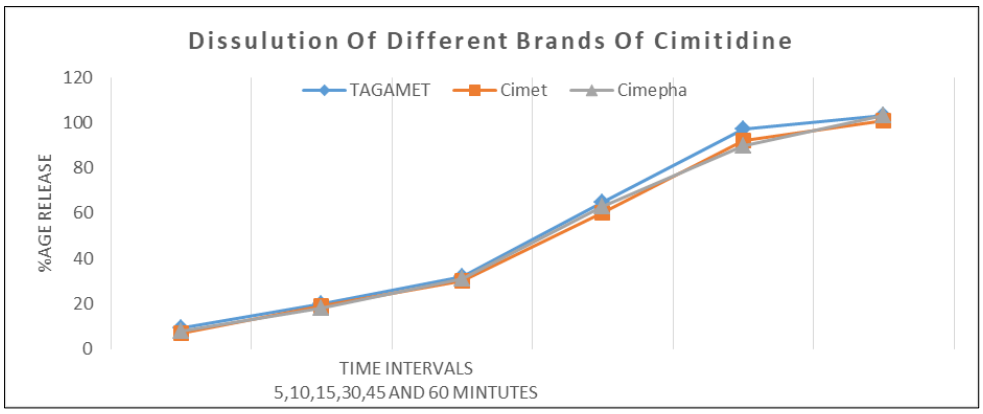

Figure 4 Dissolution Test of Cimetidine Brands

Disintegration of all various brands were checked appropriately, analyzed, and classified. It was tracked down that every one of the tablets were inside the details as indicated by the USP for example underneath than 10 minutes it implies drug organizations are observing the principles of USP.

Dissolution was performed by the predetermined principles all outcomes were found inside the cutoff points. As indicated by the USP principles.

4. Results of famotidine Brands

Table 9 Thickness test of famotidine Brands in mm

S. No	Bessfam (mm)	Famot (mm)	H2F (mm)	Zepsin (mm)	Ulfam (mm)
1	4.05	3.60	4.17	3.73	3.48
2	3.99	3.61	4.16	3.74	3.46
3	4.04	3.63	4.16	3.54	3.55
4	4.05	3.57	4.17	3.71	3.48
5	4.03	3.61	4.19	3.69	3.51
6	4.03	3.59	4.10	3.60	3.45
7	4.07	3.62	4.13	3.75	3.42
8	3.98	3.64	4.18	3.77	3.45
9	4.07	3.59	4.13	3.72	3.43
10	3.97	3.61	4.14	3.79	3.46

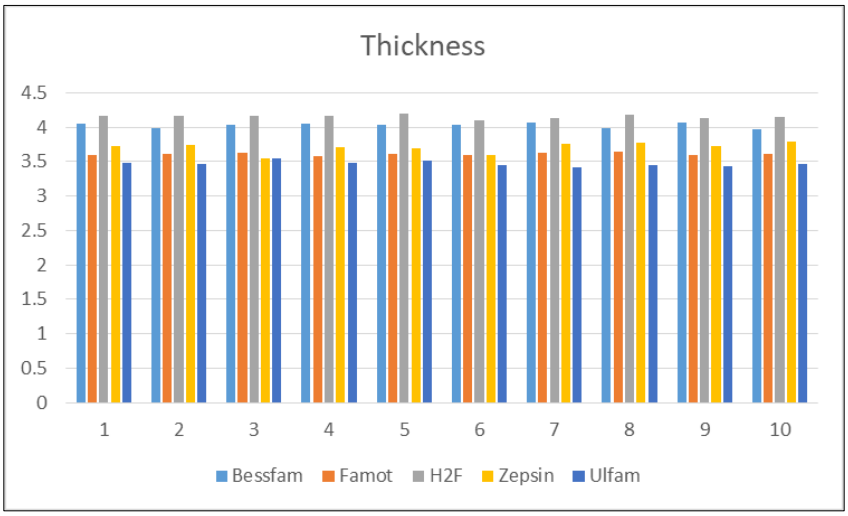

Figure 5 Thickness test of famotidine Brands in mm

Zepsin thickness ranges from 0.30 to 0.31, Famot ranges from 0.30 to 0.31, thickness ranges from 0.40 to 0.40, H2F thickness ranges from0.40 to 0.40, Bessfam thickness ranges from 0.30 to 0.30, Ulfam thickness ranges from0.30 to 0.30, Ulfam thickness ranges from 0.40 to 0.40 all brands are within acceptable rage accordingly.

Zepsin weight variation ranges from 0.18 to 0.20, Famot weight variation ranges from 0.17 to 0.20 H2F weight variation ranges from 0.28 to 0.29 Bessfam weight variation ranges from 0.12 to 0.15, Ulfam weight variation ranges from 0.16 to 0.18. All of them are within acceptable range.

Table 10 Weight variation test of famotidine Brands in gm

S. No	Bessfam (gm)	Famot (gm)	H2F (gm)	Zepsin (gm)	Ulfam (gm)
1	0.306	0.191	0.291	0.182	0.173
2	0.306	0.191	0.288	0.182	0.170
3	0.308	0.195	0.288	0.208	0.178
4	0.306	0.195	0.288	0.208	0.169
5	0.306	0.192	0.288	0.209	0.166
6	0.307	0.192	0.288	0.209	0.172
7	0.301	0.192	0.292	0.202	0.173
8	0.311	0.192	0.284	0.202	0.172
9	0.311	0.190	0.288	0.202	0.170
10	0.304	0.191	0.289	0.202	0.164
11	0.304	0.194	0.292	0.206	0.164
12	0.304	0.194	0.292	0.206	0.163
13	0.305	0.192	0.292	0.199	0.163
14	0.299	0.192	0.292	0.199	0.169
15	0.301	0.194	0.289	0.202	0.168
16	0.309	0.193	0.289	0.202	0.167
17	0.306	0.192	0.289	0.206	0.166
18	0.306	0.192	0.289	0.205	0.167
19	0.308	0.192	0.284	0.216	0.170
20	0.307	0.192	0.284	0.218	0.166

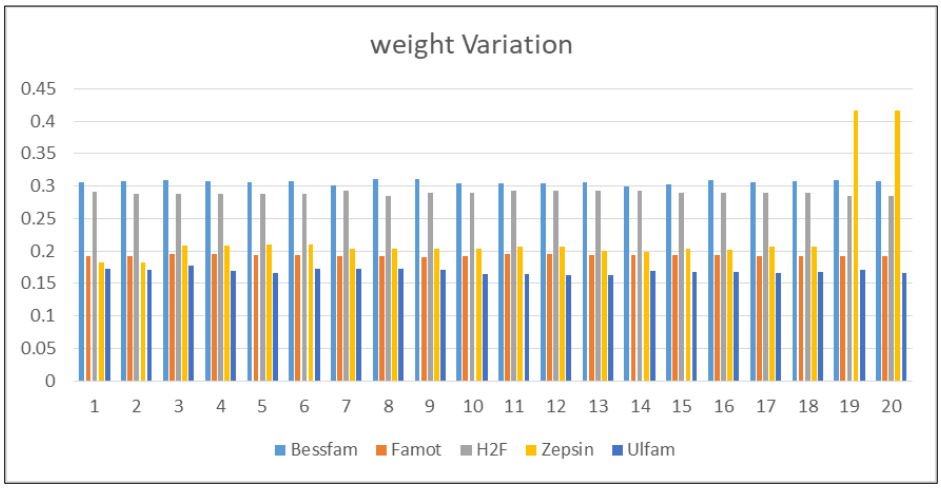

Figure 6 Weight variation test of famotidine Brands in gm

Table 11 Hardness test of famotidine Brands in kg

S. No	Bessfam (Kg)	Famot (Kg)	H2F (Kg)	Zepsin (Kg)	Ulfam (Kg))
1	7.85	8.05	8.18	7.65	7.59
2	7.95	7.62	8.11	7.59	7.98
3	7.52	8.02	8.08	8.51	7.90
4	7.81	7.95	8.12	8.25	8.01
5	7.56	7.89	7.39	7.96	8.01
6	7.58	7.91	8.32	7.89	8.21
7	7.65	8.10	7.81	8.32	8.11
8	7.25	8.01	7.89	8.02	8.01
9	7.29	7.87	8.11	7.98	7.90
10	7.33	7.99	8.10	8.12	7.89

All the brands of Famotidine were checked their hardness and found within the acceptable range.

Table 12 Friability test of famotidine Brands

Weight	Zepsin	H2F	Famot	Bessfam	Ulfam
Weight before friability	0.202	0.289	0.194	0.307	0.169
Weight after friability	0.201	0.288	0.193	0.306	0.168
Variance	0.01	0.01	0.01	0.01	0.01
%age	0.352	0.180	0.196	0.186	0.132

The outcomes were incorporated of all selected brands of famotidine and checked their Friability. The results of Friability were calculated and matched with reference determined according to the USP, which is 0.5% to 1% of their underlying weight. All the brands were accordingly.

Table 13 Disintegration test of the famotidine brands

S. N0	Product	Result
1	Bessfam	Within 5 min
2	Famot	Within 5 min
3	H2F	Within 5 min
4	Zepsin	Within 5 min.
5	Ulfam	Within 5 min

Disintegration All the formulation disintegrated with in the limited time specified as per the specifications.

Table 14 Dissolution test of famotidine brands

S. No	Brand Name	Dissolution %age
01	H2F	102.15
02	Famot	102.68
03	Bessfam	102.95
04	Zepsin	103.16
05	Ulfam	102.32

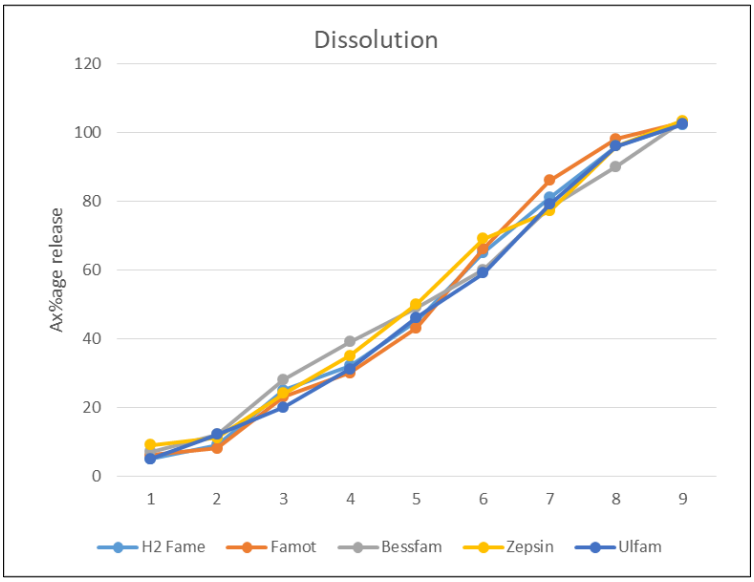

Figure 7 Dissolution of the famotidine brands

Dissolution was performed by the predetermined principles all outcomes found with cutoff points. According to the USP the resilience is not over 70% of the marked measure.

5. Conclusion

After finding inferred that tablets of various brands of cimetidine and famotidine were examined their physiochemical properties and indicated slight contrast in their physiochemical examination and discovered worthy range but found within the range according to the specifications. The weight varieties of various tried brands were inside the scope of 1%. The friability was communicated as rate misfortune and was classified and found that all the examined tablets were within the acceptable range. Tablet's hardness thickness and friability is within the acceptable range with slight differences. The disintegration and dissolution were found at acceptable limits compared with the standards of USP and BP. It is concluded that this type of research may be conducted to check the different brands of different formulations not only tablet for all the different formulations may be examined accordingly and compared with the specification. This type research may will give accurate information to the prescriber drug regulatory authorities as well as to manufacturers for best formulations available in the market and the results which are not according to the limits maybe pointed out and inform to the regulatory authorities.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest.

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