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Pharmaceutical Equivalent Analysis Work for Fexofenadine Preparations Accessible in Pakistan

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Abstract

The objective of this study is to envision pharmaceutical equivalence of various brands of Fexofenadine tablets accessible in Karachi, Pakistan. Three different brands of Fexofenadine tablets (60mg) were investigated in the study. Five quality control (QC) parameters: weight variation, thickness, hardness, friability and disintegration were applied nominative by BP/USP (British and united state pharmacopoeia). The results of study evident that the parameters like weight variation, thickness, hardness, disintegration and friability are in accordance with BP/USP. Entirely 3 brands of Fexofenadine are Pharmaceutical Equivalent.

Keywords: Fexofenadine; Weight Variation; Hardness; Thickness; Friability; Disintegration

Overview

Fexofenadine hydrochloride (FFH) is a second-generation oral antihistamine which has been widely prescribed for alleviating symptoms of Allergic rhinitis in children [1]. Fexofenadine is a non-sedating antihistamine approved for treatment of seasonal allergic rhinitis and considerably reduced pruritus severity [2]. Fexofenadine HCl is safe and effective for treatment of fall SAR, with 60 mg bid being the best therapeutic dose [3]. Fexofenadine is a selective, peripheral H1 -receptor antagonist with fast, durable activity. it's well endured, and not concomitant with sedation or cardio toxicity [4]. Fexofenadine HCl has no important consequence on QTc, even at doses > 10-fold bigger than that's efficacious for SAR [5]. Fexofenadine 180 or 240mg once daily was considerably more practical in patients with chronic idiopathic urticaria. The foremost common adverse events were headache, throat irritation, nausea, viral infection, dysmenorrhea, drowsiness, dyspepsia and fatigue. Fexofenadine encompasses a high fringe of safety and is additionally well endured in subjects with nephritic or hepatic impairment, in kids and also the aged [6]. Chronic idiopathic urticaria (CIU), characterised by the looks of itchy wheals of unknown etiology, are often staggeringly enervating and might expressively cut back a patient's quality of life (QOL) treated by Fexofenadine [7]. The second generation histamine H(1)-receptor antagonists are necessary therapeutic tools within the treatment of atopic illness and probably will have an area as an adjunct medical care for those patients whose allergic asthma coexists with allergic rhinitis [8]. The nonsedating histamine H1 receptor antagonist fexofenadine is the active metabolite of terfenadine. It reduced the allergic response in animal models of allergy and did not prolong the QT interval (QTc) in dogs or rabbits at plasma concentrations many times higher than those seen after administration of therapeutic dosages. Similarly, relative to placebo, fexofenadine did not affect mean QTc in patients given dosages of up to 480 mg/day for 2 weeks or in volunteers who received up to 800 mg/day for 6 days or 240 mg/day for 12 months. In a double-blind clinical trial, oral fexofenadine 120 or 180mg once daily controlled symptoms in patients with seasonal allergic rhinitis as effectively as cetirizine. Other double-blind clinical trials showed that fexofenadine 40 to 240mg twice daily was significantly more effective than placebo. Fexofenadine 180 or 240mg once daily was significantly more effective than placebo in patients with chronic idiopathic urticarial. The drug was well tolerated in these clinical trials, with an adverse event profile similar to that seen with placebo. The most common adverse events were headache, throat irritation, viral infection, nausea, dysmenorrhea, drowsiness, dyspepsia and fatigue [9]. Fexofenadine is administered as a racemic mixture of (R)- and (S)-enantiomers. The plasma concentrations of (R)-fexofenadine in humans are about 1.5-fold higher than those of the (S)-enantiomer. Such differences in the pharmacokinetics between fexofenadine enantiomers are likely to be dependent on stereo selectivity for affinity to drug-transporters [10]. The aim of study is to assess whether the 3 brands of Fexofenadine tablets are pharmaceutical equivalent or not. This type of study will provide a better alternative for the patient in various cases like lack of resources or unavailability of some brands. We tend to have already got been indulged in such sort of studies [11,12].

QC Parameter Testing

All the physical parameters of individually three products fexofenadine were experimental as well as paralleled. Variation in weight was checked on A.N.D Electronic Balance FX-400. For which 20 tablets of each brand is selected randomly. The percentage weight variation from average tablet weight was calculated. In order to pass weight variation test, the tablet should be within the limits of the percentage deviation allowed by BP. The degree of compaction of 10 tablet of each brand is assessed by measuring the thickness of tablets, by using VERNIER CALIPER. Hardness of all the brands is checked on MH-1, Hardness Tester of Galvano Scientific. The hardness value of each tablet was evaluated and average value was calculated and compared. Numbers of tablets were calculated to perform Friability test of each product of fexofenadine by subjecting to a uniform tumbling motion for specified period of time i.e. 25 rotations/minute for 4minutes in FB–1004 CURIO Company then the weight loss is determined. Disintegration test for all products was done on CURRO MODEL NO DS-0702. A 900 ml beaker was filled with distilled water and temperature was maintained at 37 ± 2 °C. From each product, 6 tablets of each were selected randomly and placed into the basket rack assembly and connected to the disintegration apparatus. The disintegration time for each brand is compared with the Pharmacopoeial limit specified by BP.

Result and Discussion

The purpose of this analysis work was to match and appraise standards of commercially offered 3 brands of Fexofenadine tablet in Karachi, Pakistan. Fexofenadine Tablets (60mg) were evaluated relatively for their parameters. Weight variation check of Fexofenadine tablets evidenced statistically that each of the tablets were in accordance to the BP/USP necessities as shown within the Table 1, 2 & 3. Thickness of all tablets of Fexofenadine together with standard deviation, average weight, higher & lower limits are in accordance with BP/USP as shown in the Table 4 & 5. Hardness check of Fexofenadine tablets found in accordance with BP/USP limits. Each the brands of Fexofenadine passed the hardness check i.e. average hardness of each brands was found to be greater than 4kg. Information of hardness check is given in Table 6 and 7. Friability of each brand of Fexofenadine tablets was less than 1%. Thus it's in compliance with BP/USP standards. Its information is given in Table 8. Disintegration time of each the brands of Fexofenadine is discovered. Each the tablets disintegrated at intervals couple of minutes that are in underneath the USP limits i.e. 30 minutes for uncoated Tablets. Information of disintegration check is shown in Table 9.

No. of Units	FEXET	FEXO	TELFAST
1	0.2062	0.1583	0.2027
2	0.1963	0.1799	0.2064
3	0.2069	0.1722	0.2100
4	0.2053	0.1594	0.2162
5	0.2005	0.1657	0.2081
6	0.1896	0.1701	0.2079
7	0.2047	0.1643	0.2070
8	0.2032	0.1699	0.2165
9	0.2116	0.1667	0.2122
10	0.1956	0.1533	0.2153
11	0.2117	0.1683	0.2142
12	0.1962	0.1569	0.2155
13	0.1988	0.1587	0.2116
14	0.2070	0.1628	0.2110
15	0.2040g	0.1635	0.2112
16	0.2010	0.1418	0.2078
17	0.2017	0.1683	0.2057
18	0.2024	0.1589	0.2131
19	0.2086	0.1626	0.2117
20	0.1967	0.1629	0.2129

Table 1: Weightiness of 20 units (casually nominated) of diverse products

Product	Average (Gm)	Standard deviation	Maximum (X+3S)	Minimum (X-3S)
FEXET	0.202	0.0057	0.21915	0.18485

Product	Average	Standard deviation	Maximum	Minimum
FEXO	0.1632	0.0079	0.1869	0.1395
TELFAST	0.2105	0.0038	0.222	0.199

Table 2: Statistical Weight Variations

Product	Outcome (Gm)	BP/USP Description	Deviance from BP/ USP Requirement
FEXET	0.202	Deviation should be ±7.5%	Within specified limit
FEXO	0.1632		
TELFAST	0.2105		

Table 3: Weight Variation Test

No. of Units	FEXET	FEXO	TELFAST
1	8	8	9
2	12	10	9
3	8	12	8
4	9	10	8
5	11	8	10
6	10	11	8
7	8	10	9
8	9	11	8
9	10	14	8
10	9	9	9

Table 4: Thickness of 10 tablets (mm)

Product	Average Thickness	Standard deviation	Maximum	Minimum
	(mm)		(X+3S)	(X-3S)
FEXET	9.4	1.349	13.449	5.351
FEXO	10.3	1.828	15.786	4.817
TELFAST	8.6	0.69	10.67	6.53

Table 5: Statistical Thickness

No. of Units	FEXET (Kg)	FEXO (Kg)	TELFAST (Kg)
1	10.166	3.619	18.6
2	8.228	3.895	15.17
3	8.646	4.486	12.92
4	11.318	5.434	14.3
5	11.298	4.578	15.17
6	8.463	5.006	18.02
7	15.794	5.628	15.68
8	10.879	5.271	13.84
9	10.166	3.232	13.13
10	8.565	4.812	15.88

Table 6: Hardness of 10 tablets from the optimized formulation.

Product	Average HARDNESS (Kg)	Standard deviation	Maximum	Minimum (X-3S)
FEXET	10.3523Kg	2.260	(X+3S)	3.4973

Product	Average HARDNESS (Kg)	Standard deviation	Maximum	Minimum (X-3S)
FEXO	4.5906Kg	0.794	17.1073	2.2106
TELFAST	15.271 kg	1.89442	6.9706	9.587

Table 7: Statistical Hardness Calculation

Product	Disintegration time (min)	Restrictions	Deviance from USP
FEXET	3.833	Not more than 1 hour for coated tablets	PASS
FEXO	3.000		PASS
TELFAST	2.667		PASS

Table 8: Friability Test

Product	Outcome (%)	BP/USP Description	Deviance from BP/ USP Specification
FEXET	0.946%	Not more than 1%	Intimate to the stated edge
FEXO	0.940%		
TELFAST	0.055 %		

Table 9: Disintegration Test

Conclusion

All the 3 brands of Fexofenadine are pharmaceutical equivalents. No distinction exist were ascertained in weight variation, thickness check, hardness check, friability check and disintegration testing of tablets.

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