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Pharmaceutical Equivalent Study of Losartan Potassium Formulation available in Karachi, Pakistan

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Abstract

The purpose of this study is to check pharmaceutical equivalence of altered brands of Losartan Potassium tablets available in Karachi, Pakistan. Two different brands of Losartan Potassium tablets (50 mg) were investigated in the study. Five Quality Control (QC) parameters: Weight variation, thickness test, hardness, friability and disintegration tests were carried out as specified by BP/USP (British Pharmacopoeia and United State Pharmacopoeia). The result of study revealed that all above mentioned tests are in accordance with BP/USP. Both brands of Losartan Potassium tablets are Pharmaceutical Equivalent.

Keywords: Losartan potassium; Weight variation; Hardness; Thickness; Friability; Disintegration

Introduction

Losartan is a phenyl tetrazole deputize for imidazole compound and it is an Angiotensin Receptor Blocker II (ARB II) type I antagonist and it is used in the treatment of hypertension. Administration of Losartan results in a decrease Total Peripheral Resistance (TPR) and cardiac venous return [1]. Their pharmacologic effect is similar to that of the Angiotensin Converting Enzyme (ACE) inhibitors, since they also produce the arteriolar as well as venous dilation and blocks aldosterone secretion, thus lowers the blood pressure, salt content and water retention [2]. It is the prototypic ARB. Their pharmacologic effects are similar to the ACE inhibitors [3]. They decrease the nephrotoxicity of diabetes and makes attractive therapy in hypertensive diabetics [4]. Losartan is specific or selective type I Angiotensin II receptor (AT1) antagonist. They block receptor as a result decrease in blood pressure (Rennin-Angiotensin-Aldosterone System (RAAS)) [5]. Losartan inhibit the binding of angiotensin II to type I in tissue (kidney and adrenal glands) [6]. Losartan and its active metabolites E-3174 are more potent than losartan inhibition (angiotensin II to type I) and causes vasodilation (normally AT1 → vasoconstriction + aldosteron) decrease in sodium as well as water retention but increases excretion [6]. Protein binding of losartan is 99.7% (primarily albumin) and bioavailability is 25-35% [7]. The appearance of losartan potassium is white or may be off white crystalline powder where its melting point is between 263-265°C and it is freely soluble in water. Molecular mass of losartan potassium is 462.01 [8]. Its indications are: mild to severe hypertension, diabetic nephropathy reducing risk of stroke in people with heart disease [9]. Hypergranulosis and hyperkeratosis be developed during its treatment with losartan for arterial hypertension. Long term use of losartan potassium develops angioedema [2].

QC Parameter Testing

All QC parameters and physical appearance testing of altered brands of Losartan Potassium were carried out. Variation in weight was checked on A.N.D Electronic Balance FX-400. For which 20 tablets of each brand are selected randomly. The percentage weight variation from average tablet weights was calculated. In the 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, 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. No. of tablets were calculated to perform friability test of each brand of ketotifen by subjecting to a uniform tumbling motion for specified period of time i.e., 25 rotation/min for 4 min in Fb-1004 Curio Company and the weight loss is determined. Disintegration test for all brands 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. 6 tablets of each brand 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 Pharmacopoeia limit specified by BP.

Result and Discussion

The purpose of this research work was to compare and evaluate the quality standards of commercially available two brands of Losartan Potassium Tablet in Karachi, Pakistan. Losartan Potassium Tablets (50 mg) were evaluated comparatively for their physical parameters. Weight variation test of Losartan Potassium tablets proved statistically that all the tablets were in accordance to the BP/USP requirements as shown in the Tables 1-3. Thickness of all tablets of Losartan Potassium including standard deviation, average weight, upper & lower limits are in accordance with BP/USP as shown in the Tables 4 and 5. Hardness test of Losartan Potassium tablets were found within the BP/USP limits. Both the brands of Losartan Potassium passed the hardness test i.e., average hardness of both brands was found to be greater than 4 kg but less than 10 kg. Data of hardness test is given in Tables 6 and 7. Friability of both brands of Losartan Potassium tablets was less than 1%. Therefore, it is in compliance with the BP/USP standards. Its data is given in Table 8. Disintegration time of both the brands of naproxen is observed. Both the tablets disintegrated within 20 min which are in under the USP limits i.e., within 60 min for coated tablets. Data of disintegration test is shown in Table 9.

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Conclusion

Both the two brands of Losartan Potassium are pharmaceutical equivalents. No Difference was detected in weight variation testing, thickness testing, hardness testing, friability testing and disintegration testing of tablets.

No. of Tablets	Qsartan (g)	Losartan (g)
1	155	175
2	145	167
3	153	171
4	152	176
5	149	174
6	151	164
7	150	173
8	157	177
9	160	172
10	150	172
11	150	176
12	150	173
13	155	170
14	151	167
15	153	172
16	153	175
17	143	168
18	149	176
19	152	172
20	150	168

Table 1: Weight of 20 tablets (randomly selected) of different brands.

Tablets	Average (g)	Standard deviation	Upper limit (X+3S)	Lower limit (X-3S)
Qsartan	151	3.7	162.1	139.9
Losartan	171.9	3.61	182.73	161.07

Table 2: Statistical weight variations.

Tablets	Result (g)	BP/USP Specification	Deviation from BP/USP Specification
Qsartan	151	Deviation should be ±7.5%	Within specified limit
Losartan	171.9	Deviation should be ±7.5%	

Table 3: Weight variation test.

Number of sample	Qsartan	Losartan
1	6	9
2	9	6
3	9	8
4	6	9
5	7	9
6	9	9
7	9	9
8	8	8
9	9	6
10	9	7

Table 4: Thickness of 10 tablets (mm)

No. of tablets	Average thickness (mm)	Standard deviation	Upper limit (X+3S)	Lower limit (X-3S)
Qsartan	8.1	1.28	11.94	4.26
Losartan	8	1.24	11.72	4.28

Table 5: Statistical thickness

Number of sample	Qsartan (kg)	Losartan (kg)
1	6.66	7.27
2	5.74	7.16
3	6.40	7.05
4	7.30	6.88
5	5.64	6.65
6	5.97	6.46
7	5.55	6.36
8	6.23	6.40
9	6.80	6.23
10	6.21	6.14

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

No. of tablets	Average hardness (kg)	Standard deviation	Upper limit (X+3S)	Lower limit (X-3S)
Qsartan	6.25	0.55	7.9	4.6
Losartan	6.66	0.40	7.86	5.46

Table 7: Statistical hardness calculation.

Tablets	Friability (%)	BP/USP specification	Deviation from BP/USP specification
Qsartan	0.65%	Not more than 1%	Within the specified limit
Losartan	0.035%		Within the specified limit

Table 8: Friability test.

Tablet	Disintegration time (min)	Limits	Deviation from USP
Qsartan	10.25	Not more than 60 min for coated tablets	PASS
Losartan	20		PASS

Table 9: Disintegration test.

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