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Relative Study of Different Brands of Loratadine Available in Local Market of Karachi

Alveena Sadiq*

Department of Marketing, Jinnah University for Women, Karachi, Pakistan

***Corresponding author:** Department of Marketing, Jinnah University for Women, Karachi, Pakistan, E-mail: alveenasadiq@outlook.com

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Abstract

Loratidine, Histamine H_1 receptor is one in all the popular antagonists, non-sedating used for the treatment of allergic rhinitis, urticarial and transient alleviation of signs caused by hay fever. Loratidine blocking the release and action of histamine, a natural substance within the body that is released by means of immune system at some point of an allergic reaction. Many products of loratadine are marketed which makes it difficult to pick safe, effective, and economic one. The purpose of this study is to establish similarity amongst different brands of loratadine tablets to be had in nearby market of Karachi, Pakistan. In this study three brands of loratadine (10mg) were decided on and evaluated. Six quality control parameters: weight variation test, hardness check, thickness, friability, disintegration test and dissolution test were carried out which indicated by USP. Dissolution Test performed by using paddle method (USP 2) in 900 ml of 0.1N HCl at 50 rpm. The physicochemical parameter of loratidine did not shows any variation. Results shows that selected brands comply with in acceptance limits for weight variation, hardness, thickness, friability, disintegration and dissolution, disintegration time for all brands was in 15 minutes complying with the USP standards. From this study we concluded that all available brands of loratidine have same physiochemical parameter within the specified quality control range and may be interchange if located any non-compliance due to price issue.

Key words:

Loratidine, Histamine, Antagonist, Non-Sedating, Physiochemical Parameter

Introduction

Comparative evaluation is done to check, compare and compare the first-rate widespread of commercially available local pharmaceutical brands of tablet with multinational pharmaceutical brand in Pakistan that is according to pharmacopoeial standard i.e. B.P and U.S.P. Local and Multinational manufacturers of drugs were evaluated relatively of their physical and chemical parameter[1].It is stated that marketed oral drugs will commonly sustain favourable physiochemical properties with respect to absorption, metabolism, distribution and elimination. [2] Antihistamines are broadly used in the palliative treatment in allergic conditions. They are useful for treating hay fever, urticaria, some form of pruritus, conjunctivitis, nasal discharge, mild asthma etc. A few antihistamines possess potent antiemetic effect and subsequently are often employed in the prevention and treatment of irradiation sickness, movement sickness, and nausea in pregnancy and post-operative vomiting. Antihistamine are categorised in to two group H1 antihistamines and H2 antihistamines.H1 antihistamines further divide in to two generation which is listed below in given table 1.

Group	Generation	Drug	Uses	Characteristics13
H1 antihistamines	**1st-generation antihistamines**	**Diphenhydramine** **Meclizine** **Doxylamine** **Promethazine** **Clemastine** **Dimenhydrinate** **Brompheniramine** **Hydroxyzine** **Chlorpheniramine** **Dimetindene** **Cyproheptadine**	**Antiemetic** agent Sedative agent **Anaphylactic shock** Antiallergic agent **Allergic rhinitis** and **conjunctivitis** Contact **dermatitis** **Hay fever**, **urticaria**, **angioedema**, and rhinorrhea Motion sickness	Strong sedative action **Anticholinergic side effects**

	2nd-generation antihistamine	**Loratadine** **Desloratadine** **Cetirizine** **Levocetirizine** **Azelastine** **Fexofenadine**	Antiallergic agent **Adjuvant treatment** for **anaphylactic shock**	Nonsedative /mildly sedative
H2 antihistamines		**Ranitidine** **Cimetidine** **Famotidine**	Reduce production of stomach acid	Usually used as second-line treatment or in combination with **proton pump inhibitors** (**PPIs**)

Table 1: "1st generation" such as promethazine, caused sedation and this affect daily routines of many patients. ii). "2nd generation" antihistamines have nonsedating effect. The oral antihistamines are locally available in Pakistan with different brands names.

Loratadine is a derivative of azatadine. The structure of loratidine resembles with the tricyclic antidepressants. It's more polar and less basic than the parent compound due to the addition of a carboxymethyl ester moiety. This addition decreases the central nervous system penetration of the drug. Loratadine doesn't contain an ethylamine grouping and thus has no structural resemblance to histamine. It is comparatively specific for the H1 receptor; though, at higher doses there could also be some anti-muscarinic, anti-α-adrenergic, anti-serotonergic, and anti-leukotriene activity [1]. It is widely metabolized by first-pass mechanism within the liver, generating descarbethoxy loratadine, an active antihistamine that's fourfold stronger than loratadine itself. Loratidine is a second-generation antihistamine use to manage signs and symptoms of allergic rhinitis. A lack of sedative and CNS adverse results make loratadine at the side of other second-generation antihistamine preferable over to First generation. Loratadine is potent and long acting antihistamine with selective peripheral H1-receptor antagonist activity. Loratidine binds to H1 receptor this is located on the surface of epithelial cell, endothelial cell, eosinophil, neutrophils, airway cells and vascular smooth muscle among others. H1 histamine fall below the broader umbrella of G-protein coupled receptors, and exist in a state of equilibrium among the active and inactive forms. When histamine binding with H1 Receptor facilitate a linkage between trans membrane domains III and V, stabilizing the active form of the receptor [2]. On the opposite hand anti histamines bind to a unique site at the H1 receptor favouring the in active shape. Loratadine is well absorbed and approximately metabolized reaches significant level in plasma within 15 minutes and peak levels are attained within one hour after single oral dose, while its elimination half-life is 18-24 hours. 40% of loratadine is excreted in the urine within 10 days and 42% is eliminated in the faeces. The elimination half-life is approx.10 hours for loratadine. Loratadine can be given with or without food because it does no longer impacts the pharmacokinetics. Loratadine are indicated for the relief of symptoms related to allergic rhinitis inclusive of sneezing, nasal discharge (rhinorrhoea), itching, ocular itching and burning, constant urticaria and various dermatological conditions related to allergy. Various drugs that included in 2nd generation of antihistamine, loratadine is selective for peripheral H1 receptor that has poor affinity towards CNS H1-receptor and doesn`t penetrate effectively into central nervous system. These qualities result in a lack of CNS depressant consequences which includes drowsiness, sedation and impaired psychomotor function Adverse effect of loratidine has very few; however the reported adverse effect are insomnia, headache, fatigue, drowsiness. Overdose with loratidine increase the anticholinergic Symptoms i.e. agitation, drowsiness, tachycardia, and headache.

It is advised to patient to obtain an ECG in the event of loratadine overdose. Some literature is reported on comparative In Vitro Equivalence Evaluation of Some Loratadine Generic Tablets Marketed in Bangladesh. Another report also published on a comparative study of loratidine physiochemical properties from different brands.

Aim of Study

The aim of the study is to evaluate uniformity of different brands of loratadine tablet available in Karachi. The quality of loratadine is to be compared with all aspects and will help for the selection of best brand of drug by the pharmacists or doctors. This study aims to provide confirmation of safety, effectiveness of the drugs can be used [3].

Materials and Methodology

Test performed to conduct a comparative study between 3 completely different brands of Loratidine i.e. out there in local market of city. These are coded as TIR01 (multinational brand taken as standard) and 2 local brands given serial no. as JAR02, SOF03 and tested for following physiochemical parameters in order to conduct a comparative study among the brand leader of multinational company and other local company brands. Following test parameters are measure performed to evaluate the physiochemical parameters of loratidine available brands in market of Karachi.

Weight variation: Weight variation test represented drug content uniformity. during this check ten tablets had been taken from each brand and measures the weight of each tablet by using an Electronic balance (FX-400) and average weight for every brand was performed as per specification given in Pharmacopeia and results has been recorded given in Tables i.e. 2 and 3

Thickness: Thickness showed the uniform diameter of tablet and likewise assures the degree of compaction of tablet. Ten tablets of each brand are taken to evaluate thickness and diameter by the help of using Vernier caliper.

Hardness: This test indicates the adequate mechanical strength. Hardness test is conducted on 10 tablets of each brand and applied mechanical stress on it. A tablet must be hard enough to bear stress. Hardness of all the brands is checked on MH1, Hardness Tester of Galvano Scientific. The hardness values of each tablet were evaluated, and average value was calculated and compared [4].

Friability: Friability test has been performed on ten tablets of each brand of Loratidine by subjecting to a regular tumbling motion for nominative period i.e. twenty-five rotation/minute for 4minutes in FB–1004 CURIO Company through which determine weight loss. Friability Test check is done to check, if a tablet abrades throughout transportation by taking initial and final weight and determine the weight loss.

$$\text{Friability } \% = \frac{(W1-W2)}{W1} \times 100$$

Disintegration: Disintegration test is one of the quality control tests in which Disintegration Curio apparatus (DS-0702) has been used to perform disintegration test.

This test is done to determine disintegration of tablets within the approved time once placed in a fluid medium. In this test 5 tablets of each brands has been selected and place them separately in every basket of the apparatus, then place this basket rack in 800ml beaker of water at 37˚C. Run the apparatus and disintegration time had been recorded.

Dissolution: Dissolution test had carried on selected tablets from each brand. In this test Basket type (GDT_7L from Galvano Scientific equipment is used. In this test, we make up the volume of 900ml HCL 0.1N dissolution medium in a beaker and maintained it at 37˚C.

Then place a tablet of each brands in separate beakers and operate the device at 50rpm on different time interval i.e. 0minute, 15minute, 30minute and 45 minutes.

Inject 10ml of a sample at the end at specified time intervals and analyze the sample by using UV visible spectrophotometer at 237nm and note the absorbance of each withdrawn sample and calculate the concentration of drug in sample are filtered. In vitro dissolution testing parameters [5].

Price variation study: In this study Retail Price of different brands of Loratidine tablets are noted and compared the average price of all selected brands. (Table 1)

Statistical analysis: Data were coded, recorded, and analysed statistically via Microsoft excel through which various parameters are evaluated and compared (Tables 2 and 5).

S.no	Serial no.	Batch no.	Code no.	Price/10 units pkr
1.	Lora-01	JAD025	044299	92.60
2.	Lora-02	T6783	012026	68.31
3.	Lora-03	3618005	084331	100.00

Table 2: General Table.

No.	Brands	Batch no.	Code no.	Average weight (g)	Standard deviatiion	Upper limit (x +3s)	Lower limit (x-3s)
1.	Lora-01	JAD025	044299	0.101855	0.0005	0.10355	-0.0011
2.	Lora-02	T6783	012026	0.15621	0.0015	0.16082	-0.0031
3.	Lora-03	3618005	084331	0.11257	0.0079	0.13647	-0.0159

Table 3: Statistical Weight Variation.

No.	Brands	Batch no.	Code no.	Result (g)	bp/usp specification	Deviation from bp/usp specification
1.	Lora-01	JAD025	044299	0.101855	USP SPECIFICATION	Within limit
2.	Lora-02	T6783	012026	0.15621	USP SPECIFICATION	Within limit
3.	Lora-03	3618005	084331	0.11257	USP SPECIFICATION	Within limit

Table 4: Official Limits and Results for Weight Variation Test.

No.	Brands	Batch no.	Code no.	Average hardness (kg)	Standard deviation	Upper limit (x+3s)	Lower limit (x-3s)
1.	Lora-01	JAD025	044299	3.72	0.239077	4.43723	-0.4782
2.	Lora-02	T6783	012026	4.4325	0.386644	5.59243	-0.7733
3.	Lora-03	3618005	084331	4.1725	0.211433	4.8068	-0.4229

Table 5: Hardness of different brands.

Results and Discussion

Loratidine tablets all physicochemical parameters like weight variation, hardness thickness friability, dissolution and disintegration have been performed and its shows results within specified USP limits and produces the effective results.

- Table 1 explains the coding of the brands available in market and code number, serial number is given to each brand to identify the respective one and batch number are also used for identification.
- Table 2 identify the variation in weight between all brand of loratidine and all the tablets are within upper and lower control limit specified by BP.
- Table 3 explains the average weight of loratidine brand in gm and their official limit given by USP for each weight variation range, all the brands are having weight variation within the specified range.
- Table 4 indicates the average hardness that indicates average hardness of all brands in Kg, standard deviation and (UCL=X+3S) upper and (LCL) (X-3S) lower control limit is calculated for each brand.
- Table 5 shows the thickness and uniform diameter of tablets. Thickness of each brand tablet was in range.

Conclusion

From this study we have concluded that all above discussion showed that all the available brand in market of Karachi, Pakistan are having similar physiochemical parameter with in the specified quality control range and can be exchange so it determined that all brands are equivalent in terms of physiochemical properties and price.

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