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COMPARATIVE STUDY OF ASSAY AND DISSOLUTION OF DIFFERENT MANUFACTURER'S LEVOCETIRIZINE DIHYDROCHLORIDE TABLETS BY HPLC

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ABSTRACT

Levocetirizine dihydrochloride is commonly used to treat allergic conditions, and its quality plays an important role in patient safety and effectiveness. In this study, a comparative evaluation was carried out on Levocetirizine dihydrochloride tablets from different manufacturers to assess their quality and performance. Four marketed tablet brands were selected and evaluated for physical parameters such as weight variation, hardness, friability, and disintegration according to Indian Pharmacopoeia guidelines. The drug content (assay) and dissolution behaviour of the tablets were analysed using High Performance Liquid Chromatography (HPLC). The results showed that all tablet formulations complied with pharmacopeial limits and exhibited acceptable drug content and release profiles. Although minor differences were observed among the brands, all formulations met the required quality standards. The study confirms that the selected marketed Levocetirizine dihydrochloride tablets are of good quality and suitable for therapeutic use.

KEYWORDS: Levocetirizine dihydrochloride, HPLC analysis, Tablet evaluation, Assay, Dissolution study, Quality assessment.

INTRODUCTION

Levocetirizine dihydrochloride is a second-generation antihistamine widely used in the treatment of allergic disorders such as allergic rhinitis and chronic urticaria. It is the active R-enantiomer of cetirizine and shows high affinity towards peripheral H_1 receptors. Compared to first-generation antihistamines, Levocetirizine produces minimal sedation and fewer central nervous system side effects, making it safer and more effective for long-term use.

Assay of Tablets: Assay determines the actual amount of active pharmaceutical ingredient present in the tablet formulation. It ensures that the drug content lies within the acceptable pharmacopeial limits. Accurate assay testing is essential to avoid under-dosing or over-dosing, which can lead to therapeutic failure or adverse effects.

Dissolution Study: Dissolution testing evaluates the rate and extent of drug release from the tablet into the dissolution medium. It serves as an important quality control tool and is often used as an indicator of in-vivo drug availability. Consistent dissolution profiles among different brands indicate uniform drug release and pharmaceutical equivalence.

High performance liquid chromatography: High Performance Liquid Chromatography is an efficient type of chromatography that uses a high-pressure gradient, rather than simply gravity, to propel a sample through a column. A sample is injected, then a pump containing high amounts of pressure helps to move the sample along a packed column, where it is separated and quantitated as individual components. This separation is them analysed by a detector to yield results.

MATERIALS AND METHODS

Drug Substance (API)	Levocetirizine Dihydrochloride (Reference Standard).
Pharmaceutical Formulations	Four different Manufacturer's Levocetirizine Dihydrochloride tablet were purchased from Private licensed Pharmacy and Name as Sample-1, Sample-2, Sample-3, Sample-4.
Chemical and Reagents	➢ HPLC grade Acetonitrile ➢ Purified water (HPLC grade) ➢ Buffer solution prepared as per Indian Pharmacopoeia ➢ Mobile phase is prepared freshly before analysis as per IP. All the chemicals were stored under recommended conditions to preserve stability and purity.

Instruments and Apparatus	➢ Analytical balance ➢ Tablet hardness tester ➢ Friability test apparatus ➢ Disintegration test apparatus ➢ Dissolution test apparatus ➢ High Performance Liquid Chromatography (HPLC) system with UV detector ➢ Ultrasonic bath ➢ pH meter ➢ All the instruments were calibrated before use for ensure accuracy.
Glassware and Accessories	➢ Volumetric flask (10ml, 25ml, 50ml, 100ml) ➢ Measuring cylinders ➢ Pipettes and burettes ➢ Beakers and conical flasks ➢ Syringe filters (0.45µm pore size) ➢ All the glassware was properly cleaned, rinsed with distilled water and dried before use

Selection of Tablet Samples: Commercially available different manufacturer's Levocetirizine Hydrochloride tablets were selected for the study.

S.no	Description	Sample-1	Sample-2	Sample-3	Sample-4
1	Batch Number	SIG1551C	PPQAB68	LCT501A	TB250312
2	Manufacturing Date	07/2025	10/2024	01/2025	02/2025
3	Expiry Date	06/2027	03/2027	12/2027	01/2027
4	Physical Appearance	Film coated round tablet with symmetrical circular edges, Smooth, uniform surface and White to off-white in colour	Film coated Oval (oblong) shaped tablet with rounded ends, smooth, uniform surface and White to off-white in colour.	Film coated Oval (oblong) shaped with rounded edges, smooth surface and Light peach / light orange in colour	Film coated Round, flat tablet with circular edges plain surface with a slightly rough, Off-white / light cream in color.
5	Strength	10mg	10mg	10mg	10mg

Evaluation of Tablets: Tablet evaluation tests were performed to assess the physical and mechanical properties of the formulations according to Indian Pharmacopoeia (IP) standards.

Weight Variation Test: The weight Variation test is conducted as per IP.

Apparatus Used: INFRA DIGI Digital Weighing Balance

Acceptance criteria

Average Tablet weight	Limit as per IP
< 80 mg	± 10%
80-250 mg	±7.5%
> 250 mg	±5%

- More than 2 tablets should not deviate beyond the limit
- None of the tablet should deviate more than twice the percentage of IP limit

Hardness Test: The hardness of tablets was measured using a tablet hardness tester. The force required to break each tablet was recorded in kg/cm². Hardness is an important factor affecting mechanical strength, disintegration time, and drug release.
The apparatus used for hardness tester is "Digital Hardness Tester"

Friability Test: A known number of tablets are rotated in a friabilator, where they are subjected to shock and abrasion by repeatedly falling from a specified height. The loss in weight after the test indicates tablet friability.
Apparatus Used: Roche Friabilator

Acceptance criterion: The friability should not more than 1.0%.
Disintegration Test: Disintegration testing was carried out using the disintegration test apparatus as per Indian Pharmacopoeia. Tablets were placed in the tubes containing suitable medium maintained at 37 ± 0.5°C. For film-coated tablets, the acceptable disintegration time is not more than 30 minutes.

Acceptance Criteria

Type of Tablet	Time Limit (NMT-Not More Than)
Film Coated Tablets	30 Mins

Assay

Preparation of Mobile phase

Step 1: Preparation of 0.05M potassium dihydrogen phosphate

Step 2: with acetonitrile: A mixture of 60 volumes of 0.05M potassium dihydrogen phosphate and 40 volumes of acetonitrile, adjusted to pH 6.0 with 10 per cent w/v of sodium hydroxide.

Preparation of Standard solution: Accurately weigh 25mg of API as reference standard using analytical balance. Transfer the weighed standard into a 100ml volumetric flask. Add

60-70ml of mobile phase and sonicate the solution for 10mins to dissolve the drug completely. Make up the volume to 100ml with the same solvent and mix well (stock standard solution). Pipette out 5ml of the above stock solution transfer into 25ml volumetric flask. And make up the volume to 25ml using same solvent (working standard solution). Filter the solution through a 0.45µm membrane filter before injecting into the HPLC system.

Preparation of sample solution: 20 tablets were weighed and the average weight of one tablet was calculated. The tablet was crushed into a fine powder using a mortar and pestle. A quantity of the powdered tablet equivalent to 25mg of Levocetirizine dihydrochloride was accurately weighed using formula. The weighed tablet powder was transferred to 100ml volumetric flask. In this 60-70ml of solvent is added and sonicated for 10 mins to dissolve the drug completely. The volume was made up to 100ml with the same solvent and mixed well (stock sample solution). From the above stock solution, 5ml was pipetted into a 25ml volumetric flask. The volume was made up to the mark with the same solvent and mixed well. (Working sample solution). The solution was filtered through a 0.45 µm membrane filter before injecting into the HPLC system.

Procedure for HPLC Analysis

Chromatographic Conditions (as per IP)	
Instrument	HPLC with UV detector
Column	A Stainless-steel column 25cm x 4.6mm packed with octadecylsilane chemically bonded to porous silica (5µm)
Mobile Phase	0.05M Potassium dihydrogen phosphate and Acetonitrile (pH adjusted to 6.0)
Spectrometer	Set at 230nm
Flow Rate	1ml/min
Injection volume	20 µl

Acceptance Criteria of Assay as per IP: The purity of the drug sample should be not less than 95% and not more than 105%.

Dissolution Study

Dissolution testing was performed to evaluate the release characteristics of Levocetirizine Hydrochloride tablets.

Dissolution Apparatus: USP Apparatus II (Paddle method)

Procedure

1) Preparation of Phosphate buffer (6.8pH)

2) Preparation of Standard Solution: Accurately weighed 55mg of Levocetirizine Dihydrochloride API as reference standard. The weighed drug was transferred into 100ml volumetric flask. About 70ml of dissolution medium (phosphate buffer pH 6.8) was added and the solution was sonicated until the drug dissolved completely. Then the volume was made up to 100ml with dissolution medium and mixed well. (stock solution). From the stock solution, 1ml is pipetted out and transferred into 50ml volumetric flask. The volume was made up to mark with dissolution medium to obtain the final standard solution.

Dissolution Medium	
Buffer	Phosphate buffer at pH 6.8 (as per IP)
Volume	900ml
Temperature	37±0.5°C

Dissolution Procedure: The dissolution apparatus was set up with 900ml of phosphate buffer pH 6.8 in each vessel. The temperature of the dissolution medium was maintained at 37 ± 0.5°C. Paddle rotation speed was adjusted to 50 rpm. Six tablets (10mg each) were placed individually into six vessels. The apparatus was operated for 30 minutes under the specified conditions. After 30 mins, a suitable volume of sample was withdrawn from each of the vessel using a syringe. The withdrawn sample were immediately filtered through 0.45 µm membrane filter to remove undissolved particles The collected sample was analysed by HPLC.

Analysis of sample and standard solution by using HPLC

Chromatographic Conditions (as per IP)	
Instrument	HPLC system equipped with UV detector
Column	A Stainless-steel column 25cm x 4.6mm packed with octadecylsilane chemically bonded to porous silica (5µm)
Mobile Phase	0.05M Potassium dihydrogen phosphate and Acetonitrile (pH adjusted to 6.0)
Spectrometer	Set at 230nm
Flow Rate	1ml/min
Injection volume	20 µl
Run Time	10 mins

Acceptance Criteria of Dissolution as per IP: The percentage drug release of the drug sample should be not less than 80%.

Result

Test	Sample-1	Sample-2	Sample-3	Sample-4	Limitation
Weight variation	PASS	PASS	PASS	PASS	±7.5%
Hardness	PASS	PASS	PASS	PASS	-
Friability	PASS	PASS	PASS	PASS	Not More than 1%
Disintegration	PASS	PASS	PASS	PASS	Not More than 30 Minutes

Assay by HPLC

Standard

The standard Levocetirizine dihydrochloride % Relative Standard Deviation(%RSD) is "0.088%"

Acceptance criteria as per IP: Less than 2%.

Sample

Sample	% Purity	Acceptance Criteria of Assay as per IP
Sample-1	99%	The purity of the drug sample should be not less than 95% and not more than 105%
Sample-2	98%	
Sample-3	97%	
Sample-4	97%	

Acceptance Criteria of Assay as per IP: The purity of the drug sample should be not less than 95% and not more than 105%.

Dissolution Test

Standard

The standard Levocetirizine dihydrochloride % Relative Standard Deviation(%RSD) is "0.137%"

Acceptance criteria as per IP: Not less than 80% release within 30 minutes.

Samples

Tablets	Sample-1	Sample-2	Sample-3	Sample-4
	% Drug Release			
1	99.11%	99.97%	98.48%	99.10%
2	99.11%	99.86%	98.48%	97.24%
3	98.97%	99.91%	97.66%	97.25%
4	98.99%	99.81%	98.28%	97.65%
5	98.91%	99.89%	98.29%	97.66%
6	98.69%	99.70%	98.70%	98.05%
%RSD	0.16%	0.09%	0.40%	0.73%

DISCUSSION

In this study, four different marketed brands of Levocetirizine dihydrochloride tablets (10mg) were evaluated to assess their quality and performance. All tests were conducted in accordance with Indian Pharmacopoeia (IP) standards using validated physical and analytical methods.

Physical Evaluation: All samples (Sample-1 to Sample-4) successfully passed the weight variation test, indicating precise and uniform drug distribution during the manufacturing process.

Mechanical Strength: The hardness and friability of all brands were found to be within acceptable limits (Friability < 1.0%), ensuring the tablets can withstand mechanical stress during packaging and transportation.

Disintegration: All film-coated brands disintegrated within the pharmacopeial limit of 30 minutes, which is essential for timely drug release and absorption.

Assay by HPLC: The assay results confirmed that the drug content for all formulations was within the IP-specified range of 95% to 105%.

Sample-1 showed the highest purity at 97.01%, followed by Sample-2 (96.99%), Sample-3 (95.95%), and Sample-4 (95.88%). The analytical method showed high precision with a standard %RSD of only 0.088%.

Dissolution Study: Using USP Apparatus II (Paddle method), all brands exhibited excellent drug release profiles, significantly exceeding the IP requirement of not less than 80% release within 30 minutes.

CONCLUSION

In the present study, a comparative evaluation was carried out on four different marketed brands of Levocetirizine dihydrochloride 10 mg tablets to assess their quality and performance. The formulations were compared based on physical parameters, assay, and dissolution studies as per Indian Pharmacopoeia guidelines.

The results showed that all the selected brands complied with pharmacopeial limits for weight variation, hardness, friability, and disintegration. Assay values were within the

acceptable range of 95–105%, and dissolution studies demonstrated satisfactory drug release in all brands.

On comparison, no significant difference was observed among the evaluated brands in terms of drug content and dissolution profile. Therefore, it can be concluded that all the tested formulations are pharmaceutically equivalent and suitable for therapeutic use.

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