International Journal of Scientific Research and Engineering Development-– Volume 7 Issue 4, July-Aug 2024
Available at www.ijsred.com

RESEARCH ARTICLE OPEN ACCESS

A Review on analytical Methods for Hydrochlorothiazide and Losartan Potassium

B. Pavani*, S. Vanisri, T. Rama Rao
Department of Pharmaceutical Analysis, CMR College of Pharmacy, Hyderabad, Telangana, India
*Corresponding author: B. Pavani
Email Id:Pavani.didigam@gmail.com

ABSTRACT:
Hydrochlorothiazide is a diuretic medication used to treat hypertension and swelling due to fluid build-up. Hydrochlorothiazide is a thiazide medication which inhibits reabsorption of sodium and chloride ions from the distal convoluted tubules of the kidneys, causing a natriuresis. This initially increases urine volume and lowers blood volume.Losartan is a medication used to treat high blood pressure (hypertension). It is in the angiotensin receptor blocker (ARB) family of medication, and is considered protective of the kidneys. Besides hypertension, it is also used in diabetes, kidney disease, heart failure, and left ventricular enlargement.Losartan potassium and hydrochlorothiazide is a combination of two medications that work together to lower blood pressure.Various analytical methods such as High-performance liquid chromatography (HPLC), High-performance thin layer chromatography (HPTLC), and UV-Spectrophotometric methods have been developed for the estimation of Hydrochlorothiazide single and combinations with Losartan Potassium have been reported.

Keywords: Hydrochlorothiazide, Losartan Potassium, UV-Visible Spectroscopy, HPLC and HPTLC.

I. INTRODUCTION

The chemical name for Losartan Potassium (LOS) is [4(2hydroxy3isopropylaminopropoxy) phenylacetamide], and it functions as both an inverse and competitive agonist of A-II. Hydrochlorothiazide (HCT) is a diuretic that is 6-Chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide.

One drug may affect the estimation of another medicine when analyzing a multicomponent dosage form chemically. As a result, analytical techniques are created to assess each drug in a multicomponent formulation simultaneously.

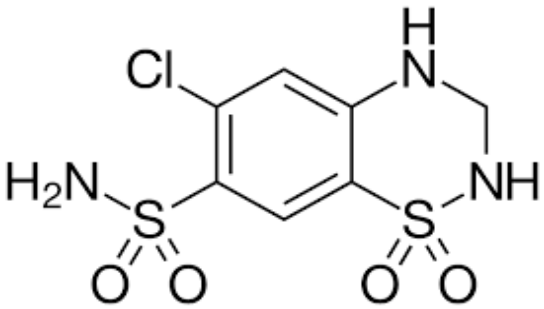

Fig. 1 Chemical structure of Hydrochlorothiazide

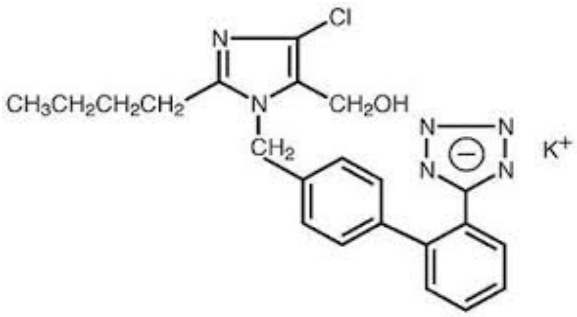

Fig. 2Chemical structure of Losartan Potassium

II. LITERATURE REVIEW

UV-SPECTROSCOPIC METHODS:

Neela M Bhatia et al.,[1] 2013: Hydrochlorothiazide and losartan potassium are combined to treat hypertension. The current work focuses on developing a straightforward spectrophotometric approach for the simultaneous determination of hydrochlorothiazide (HCT) and losartan potassium (LOS) in two-component tablet formulation. In first order derivative spectroscopy, 20 µg/ml of LOS and HCT were scanned in a range of 200–400 nm to determine the sampling wavelength. For LOS, the sampling wavelength was 257 nm, where HCT exhibited zero crossing point, and for HCT, it was 243 nm, where LOS showed zero crossing point. Linearity was observed in the range of 2.5–22.5 µg/ml for HCT and 10-90 µg/ml for LOS using this approach.

Chaitali Thubeet al.,[2] 2014: The absorbance maxima of losartan potassium and hydrochlorothiazide were determined in method I at 235 nm and 271 nm, respectively. Using the absorptive values computed for both medications at wavelengths of 235 nm and 271 nm, the concentration of each drug was determined. Losartan potassium and hydrochlorothiazide were quantified using Method II's dual wavelength approach based on the idea that the absorbance difference between two locations on a mixture spectrum was directly related to the concentration of the component of interest and unaffected by other components. Method III, which defines Area under Curve, measures the area under curve for the analysis in methanol in the range of 229–242 nm (For HCTZ) and 265-282 nm (For LOS). The concentration range of 5-30µg/ml for hydrochlorothiazide and losartan potassium showed a linearity range.

Hapse. S. A et al.,[3] 2012:A technique for estimating the dosage of hydrochlorothiazide in tablet form has been developed. The analytical technique designed to determine the amount of hydrochlorothiazide in large volumes of fluids demonstrated its highest absorbance at λmax of 272 nm in distilled water and 0.01N NaOH in the UV scan range of 200 nm to 400 nm. Research on linearity revealed that the estimation of hydrochlorothiazide in distilled water ranged from 5.00µg/ml to 30.00µg/ml, and in 0.01N NaOH, from 1.00µg/ml to 30.00µg/ml. The regression equations were y = 0.043x+0.198; r2 = 0.999, and y = 0.059+0.029; r2 = 0.998.

Pawar Seemarani et al., [4] 2017:AUC technique estimation of hydrochlorothiazide medication has been developed. Double-distilled water was used as a solvent in the preparation of the standard and sample solutions. The drug's quantitative determination was carried out in the wavelength region of 222-228 nm. With a correlation coefficient value of 0.9979, the linearity of hydrochlorothiazide was established over the concentration range of 02–10 µg/ml. According to precision studies, the percentage relative standard deviation fell within the permissible bounds. The average recovery percentage was discovered to be 99.39%.

Bharadet al.,[5] 2022:A technique for estimating the medication formulation of hydrochlorothiazide has been devised and validated. With a correlation coefficient of 0.9995, hydrochlorothiazide's absorption maxima were shown to be at 271.0 nm and its absorption was linear over a range of 5µg/ml–25µg/ml. The precision and accuracy-recovery investigations were used to validate the suggested analytical approach. It was discovered that the accuracy-recovery percentages for the three different levels—50%, 100%, and 150%—were 50.1%, 99.5%, and 151.1%, respectively.

Kiran rapoluet al.,[6]2024: For the purpose of estimating the formulation and pure amount of hydrochlorothiazide, a method has been developed and verified. With a correlation coefficient of 0.996, hydrochlorothiazide demonstrated an absorption peak at 270 nm and a linear response throughout a range of 2–10 µg/ml. Precision and accuracy investigations were conducted in order to validate the above-proposed approach. Good intra

precision (repeatability) with a relative standard deviation of 0.24% and inter precision with a relative standard deviation of 0.68%, less than 2, were demonstrated by the analytical procedure. The percentage recovery was found to be 95.01%, 99.33%, and 101.66% at three distinct levels, i.e., 80%, 100%, and 120%.

PermenderRatheeet al.,[7]2008: After scanning the UV spectrum from 220 to 400 nm, the highest wavelength for absorption was determined to be 227.4 nm. In the concentration range of 2.02-22.22 µg/ml, Beer's law was followed. Excipient interference was avoided when the method was successfully applied to the pharmaceutical dosage form containing the drug in question, yielding good accuracy (98.11-99.85%), precision (RSD 0.303-0.334), and selectivity (= 0.5%). The analysis's findings were confirmed by recovery studies and in accordance with ICH recommendations.

Kareti raoet al.,[8] 2011: In this study, three distinct approaches are used to simultaneously determine the levels of hydrochlorothiazide (HZ) and losartan potassium (LSP) in a binary mixed form without any prior separation. The Shimadzu electron UV1800 double beam UV-visible spectrophotometer was used for the current experiment. The solvents are distilled water and methanol from Merck Ltd. The use of simultaneous equations is the first technique. For LSP and HZ, the corresponding linearity ranges were 5–25 µg/ml and 1–20 µg/ml respectively. The second technique measures the ratio of absorbance at 272 nm, the isosbestic wavelength of 266.5 nm, and the maximum absorption of HZ. For LSP and HZ, the linearity ranges were 5-80µg/ml and 1-25µg/ml respectively.The linearity ranges for LSP and HZ in the third approach, the first order derivative method, were 1–30 µg/ml and 1–40 µg/ml respectively. By utilizing the standard addition technique, the validity of the proposed methods was evaluated. For LSP and HZrespectively, the percentage recovery of the added standard was found to be 99.06[+ or -] 1.210 and 99.30[+ or -]1.159 using the simultaneous equation method, 99.66[+ or -]0.573 and 99.95[+ or -]0.272 using the graphical absorbance ratio method, and 99.64[+ or -]0.301 and 99.91[+ or -]0.614 using the first derivative method.

Tran Thuc Binh et al.,[9] 2021: This study uses chemometrics and UV-visible spectrophotometry to simultaneously evaluate the contents of tablets containing hydrochlorothiazide (HCT) and losartan potassium (LSP) without separation. At 1.0 nm intervals, the spectra of the standard and sample solutions were recorded in the wavelength range of 220 to 300 nm. By comparing the mean values of the HCT and LSP contents in the sample with those evaluated using HPLC, the accuracy and repeatability of measurements during the analysis of the Splozarsin Plus tablet were used to assess the technique validation.

Özgür ÜSTÜNDAĞ et al.,[10] 2021: This work detailed the invention of a spectrophotometric approach for the simultaneous determination of losartan potassium and hydrochlorothiazide in tablets using a continuous wavelet 963 transform methodology. Examining the original UV spectra of hydrochlorothiazide and losartan potassium reveals a significant overlap between their spectra. Without requiring a pre-separation procedure, the analysis was completed effectively using the created Symlets5-CWT approach. For the determination of losartan potassium and hydrochlorothiazide, the calibration equations were found at 247.7 nm and 259.1 nm, respectively.

HPLC METHODS:

Md. Arif Hossen et al.,[11] 2011: A mobile phase consisting of 0.025 M phosphoric acid solution: acetonitrile (60:40 v/v, pH 3.0 adjusted with 80% phosphoric acid) was employed in conjunction with a shim-pack CLC-ODS column (250 mm X 4.6 mm, 5µ). The flow rate was 1.5 ml/min, and a UV detector with a wavelength of 254 nm was used for detection. Losartan potassium and hydrochlorothiazide had retention periods of 8.790 and 3.748 minutes, respectively. Losartan

potassium and hydrochlorothiazide peaks were well separated (resolution 22.17). Over the concentration range of 80% to 120%, the calibration curves were linear (R2 > 0.999 for both medications). The suggested approach is exact (% RSD < 0.5) and accurate, recovering 100.165% for hydrochlorothiazide and 100.422% for losartan potassium.

Vivekanandan. N et al,[12] 2022: For the simultaneous measurement of hydrochlorothiazide and losartan potassium in pharmaceutical tablet dosage form, the RP-HPLC method was devised and validated. Utilizing the mobile phase (Acetonitrile: Buffer B (7:93 v/v) pH 7.0 to 7.5 with 0.05% at a flow rate of 1.0 ml/min, injection volume 20 µl, and UV detection at 280 nm, the RP-HPLC procedure was carried out on the HPLC System with UV-VIS detector and Nucleodur,C8 (150 mm × 3.9 mm, 5 µm). For Losartan potassium and hydrochlorothiazide, respectively, linear relationships were found in the ranges of 100-300 µg/ml and 50-150 µg/ml with correlation coefficients of 0.9999 and 0.9996 at rt values of 10.769 min and 21.633 min.

Nidhal M. Sher Mohammed et al.,[13] 2019: For the simultaneous measurement of hydrochlorothiazide and losartan in bulk and pharmaceutical formulation, the HPLC-UV method was created and validated. The procedure was optimized by choosing ACE3-C18 column (250 mm × 4.6 mm 5 µm), 20 µl injection volume, 1 ml/min flow rate at room temperature (25 °C), and 226 nm as the chromatographic conditions. Good accuracy (RSD% < 1), adequate linearity (R2 ≥ 0.997), and low LOD and LOQ (0.5 and 1.5 µg/ml, respectively) were obtained upon validation of the method.

Sibel A. Özkan[14]2001: The simultaneous determination of losartan potassium and hydrochlorothiazide from tablets and human serum can be achieved with the RP-HPLC method. Using a combination of 0.01 M KH2PO4: acetonitrile (65:35; v/v) adjusted to pH 3.1 with H3PO4 at a flow rate of 1.0 mL/min, chromatography was performed on a C18 reversed-phase column. A UV detector was used to realize the detection at 232 nm. Linearity was found for losartan potassium in the concentration range of 25–10000 ng/mL and hydrochlorothiazide in the range of 50–10000 ng/mL. For losartan potassium, 1.02 ng/mL and 3.39 ng/mL were found to be the procedure's limit of detection; for hydrochlorothiazide, the limits were 4.49 ng/mL and 14.96 ng/mL.

A.P Argekar et al., [15] 2008: For the simultaneous measurement of hydrochlorothiazide (HCT) and losartan potassium (LOS) in tablets, the RP-HPLC method has been devised. Microbondapak C18 column (10 µ, 300 mm × 3.9 mm ID) served as the stationary phase. For the separation, a gradient elution using an aqueous methanolic mobile phase (pH=3) was used. A UV detector was used for the 270 nm detection. For HCT and LOS, the retention periods were 7.89 and 15.15 minutes, respectively, and the flow rate was 1.0 ml/min. For HCT and LOS, the concentration ranges of 0.5 - 200 µg/ml and 2 - 800 µg/ml were found to exhibit linearity. For HCT and LOS, the mean percentage recoveries were 100.29% and 99.16%, respectively.

HPTLC METHODS:

Shailesh A Shah et al .,[16] 2001: Using the first-derivative responses at 271.6 nm for LST and 335.0 nm for HCTZ in the spectra of respective solutions in water, the amounts of LST and HCTZ in mixed preparations were measured. With correlation coefficients of 0.9998 and 0.9997, respectively, the linearity ranges for LST and HCTZ are 30–70 µg/mL and 7.5–17.5 µg/mL, respectively. LST and HCTZ in a mixture were resolved using the HPTLC method using a prewashed Silica Gel G60 F254 TLC plate as the stationary phase and a mobile phase of chloroform–methanol–acetone–formic acid (7.5 + 1.5 + 0.5 + 0.03, v/v). For LST and HCTZ, two distinct and well-separated peaks were found, with Rf values of 0.61 ± 0.02 and 0.41 ± 0.02, respectively. At 254.0 nm, LST and HCTZ were quantified. The HPTLC approach yielded linearity ranges of 400–1200 and 100–300 ng/spot, respectively, for LST and HCTZ, with

corresponding correlation values of 0.9944 and 0.9979.

Gawande V. V. et al., [17] 2019: The analytes were resolved using a solvent solution consisting of chloroform, methanol, and ethyl acetate (4:2:2 v/v/v) and a 15-minute saturation time on precoated silica gel 60 F254 TLC plates that had been prewashed with methanol. At 255 nm, the analytes were located. The components were resolved using hydrochlorothiazide (0.83 ± 1.95) and losartan potassium (0.59 ± 1.98) retention factors. For losartan potassium, the approach guaranteed linearity in the concentration range of 600–1000 ng/spot, and for hydrochlorothiazide, 300–500 ng/spot. The method's accuracy was evaluated and determined to be up to 100% ±2.

Other methods:

Atyurmila Chakraborty et al.,[18] 2023: The review illustrates that, of the different analytical methods used for the estimation of hydrochlorothiazide, the hyphenated method was most frequently used in particular liquid chromatography in conjunction with mass spectroscopy.The calibration of the validation parameters—linearity, LOD, and LOQ—for each drug alone and in combination was accomplished with success. For chemical variables, the efficacy of analytical procedures was assessed and improved. It is advised that green chemistry be included in the improved techniques for assessing hydrochlorothiazide for future development.

CONCLUSION:

The current analytical techniques for the determination of hydrochlorothiazide and losartan potassium are covered in the systematic review that is presented. The most popular use of UV techniques were discovered for losartan potassium and hydrochlorothiazide. The determination of hydrochlorothiazide and losartan potassium also makes use of additional analytical techniques like HPLC, HPTLC, and others. Researchers working in the formulation development and quality control of hydrochlorothiazide and losartan potassium will find the material offered beneficial for their future research.

ACKNOWLEDGEMENTS

Working under the direction of B. Pavani Associate Professor, Department of Pharmaceutical Analysis has been a privilege. I would like to extend my profound appreciation to the person who helped us to see things more clearly, who really cares about the development of my review article, and without whom our work would not have progressed to this point. I would like to take this opportunity to thank our esteemed principal, Dr.T .Rama Rao, for providing the infrastructure needed to complete the review process effectively.

REFERENCE:

1.Neela M Bhatia et al., Simultaneous Estimation Of Losartan Potassium And Hydrochlorothiazide From Tablets By First Order Derivative Spectroscopy, International journal of pharmacy and pharmaceutical sciences,2013, 1(5),464-466.

2. Chaitali Thube et al., Simultaneous estimation and validation of losartan potassium and hydrochlorothiazide in bulk and tablet dosage form by using different spectrophotometric method, Scholars Research Library Der Pharma Chemica, 2014, 6 (2), 24-30.

3.Hapse . S. A et al., Spectrophotometric estimation and validation of hydrochlorothiazide in tablet dosage forms by using different solvents , Scholars Research Library Der Pharma Chemica, 2012, 4 (1), 10-14.

4. Pawar Seemarani et al., Development and validation of uv spectrophotometric estimation of hydrochlorothiazide in bulk and tablet dosage form using area under curve method, journal of bio innovation,2017,6 (6),945-951.

5.Bharad et al., Analytical method development and validation for estimation of hydrochlorothiazide content using uv-spectroscopic technique ,Journal of Advanced Scientific Research,2022, 13 (5),131-136.

6. Kiran Rapolu et al., Development and Validation of UV Spectrophotometric Method for the Determination of Hydrochlorothiazide in Pure and Formulations, International journal of pharmacy and pharmaceutical research,2024, 30(4),304-312.

7. PermenderRathee* et al.,Development And Validation Of A Stability Indicating UV-Spectrophotometric Method For The Estimation Of Losartan Potassium In Bulk And Tablet Dosage Form,Journal of Pharmacy Research, 2008,2(1),188-192.

8.Kareti Rao et al ., Spectrophotometric methods for the simultaneous estimation of losartan potassium and hydrochlorothiazide in tablet dosage forms ,Medknow Publications and Media Pvt. Ltd,2011,3(2), 2011.

9. Tran Thuc Binh et al., Simultaneous Determination of Hydrochlorothiazide and Losartan Potassium in Pharmaceutical Product by UV-Visible Spectrophotometric Method with Kalman Filter Algorithm, Hindawi Journal of Analytical Methods in Chemistry, 2021,1-8.

10.Özgür ÜSTÜNDAĞ et al.,Spectrophotometric Determination of Losartan Potassium and Hydrochlorothiazide in tablets by Wavelet Transform Approach, Sakarya University Journal of Science, 2021, 25(6), 1432-1437.

11.Md. Arif Hossen et al., 2011,Development and Validation of RP-HPLC Method for the Simultaneous Estimation of Hydrochlorothiazide and Losartan Potassium in Tablet Dosage Form,Journal Of Pharmaceutical Sciences, 10(1),35-42.

12. Vivekanandan et al,Development And Validation Of Rp-HPLC Method For The Simultaneous Estimation Of Losartan Potassium And Hydrochlorothiazide In Bulk And Tablet Dosage Form,International Journal of Chemical & Pharmaceutical Analysis, 2022, 10(1).

13.Nidhal M. Sher Mohammed et al., Method Development And Validation Of Simultaneous Determination Of Hydrochlorothiazide And Losartan In Tablet Dosage Form By Rp-Hplc,2019,10(1),1000-1005.

14.Sibel A. Özkan,Simultaneous Determination Of Losartan Potassium And Hydrochlorothiazide From Tablets And Human Serum By RP-HPLC, Journal of Liquid Chromatography & Related Technologies, 2007, 2337-2346.

15. A.P Argekaret al.,A Gradient Reversed Phase High Performance Liquid Chromatography Method for Simultaneous Determination of Hydrochlorothiazide (HCT) and Losartan Potassium (LOS) from Tablets,2008,869-880.

16. Shailesh A Shah et al, Simultaneous Determination of Losartan and Hydrochlorothiazide in Combined Dosage Forms by First-Derivative Spectroscopy and High-Performance Thin-Layer Chromatography,Journal of AOAC INTERNATIONAL, , 2001 ,6(84), 1715–1723.

17.Gawande V. V. et al.,A Validated High Performance Thin Layer Chromatographic Method For Losartan Potassium And Hydrochlorothiazide In Combination, Indian Drugs Journal, 2019,11(56).

18.Atyurmila Chakraborty et al.,Bioanalytical methods and extraction techniques for the quantification of hydrochlorothiazide and its pharmaceutical combinations: A comprehensive review, Acta Chromatographica journal, 2023,1-26.

