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RP UFLC Method Development Validation And Optimization Of Valsartan Tablet

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ABSTRACT

We have successfully developed a reverse phase Ultra Fast Liquid Chromatography (UFLC) method that is both simple and sensitive, allowing for rapid and precise estimation of valsartan in pharmaceutical dosage forms. To establish the chromatographic conditions, we utilized a C18 analytical phenomenal (Kinetex) column with dimensions of 250x4.6mm and a particle size of 5 microns. The mobile phase employed in this method consisted of a 60:40 ratio of phosphate buffer (pH 3.5) and acetonitrile. To ensure accuracy, a sample volume of 20 microliters was injected into the HPLC system after degassing the mobile phase using a Sonica ultrasonic sonicator. The flow rate was maintained at 1 ml per minute, and a wavelength of 273 nm was selected for detection purposes. The column temperature was set at ambient conditions throughout the analysis. We conducted a thorough validation of the developed method, considering various parameters such as accuracy, precision, linearity, limit of detection, limit of quantitation, and solution stability. This validation process ensured the reliability and robustness of our method for estimating valsartan in different dosage forms. Our proposed method offers several advantages, including simplicity, sensitivity, rapidity, precision, and cost-effectiveness. It can be effectively employed for the estimation of valsartan in pharmaceutical dosage forms.

KEYWORDS: Ultra Fast Liquid Chromatography, Method development, Method validation, Valsartan.

INTRODUCTION

Validation is essential to ensure the reliability and consistency of new techniques. There are different types of validation processes: prospective validation, concurrent validation, retrospective validation, and revalidation. Prospective validation involves validating a method before its use, while concurrent validation occurs during its use. Retrospective validation validates an already established method. Revalidation is necessary when a significant modification is made to the method or instrument. These validation processes guarantee the reliability of newly developed methods. It is important to prioritize the validation process to ensure that the validated method has a significant impact on the product. Detailed and comprehensive validation protocols are crucial for efficient validation processes. Additionally, the study emphasizes the importance of using High-Performance Liquid Chromatography (HPLC) instruments in the pharmaceutical industry for analyzing complex mixtures. HPLC offers high resolution, accuracy, and reproducibility in separating and analyzing complex mixtures. However, HPLC has limitations such as the need for specialized personnel and high equipment and maintenance costs. In conclusion, developing new methods for non-pharmacopoeial products can reduce costs and improve outcomes, but it is crucial to validate those using reliable processes and instruments like HPLC.

Method Development

When official methods for analyzing new products are not available, alternate methods are introduced as a viable option. These alternate methods are not only beneficial for new products but also for existing non-pharmacopoeial products. They offer advantages such as improved precision and potency while reducing the time and cost required for analysis. However, it is crucial to conduct a thorough comparison of laboratory data between the alternate and existing procedures. This comparison helps in identifying the advantages and limitations of utilizing alternate methods. By doing so, researchers and analysts can make informed decisions about the most suitable approach for their specific needs. One widely employed method in the pharmaceutical industry for analyzing complex mixtures is High-Performance Liquid Chromatography (HPLC). HPLC methods primarily aim to separate and quantify the main active drug, reaction impurities, synthetic intermediates, and degradants present in the mixture. Through this process, valuable information about the quality, purity, and potency of the product can be obtained. HPLC offers several advantages, including high resolution, accuracy, and reproducibility, making it a popular choice in pharmaceutical analysis. Its ability to provide reliable and precise data contributes to ensuring product quality. However, it is important to acknowledge the limitations of HPLC as well. For instance, HPLC can be expensive to set up and maintain due to the specialized equipment and materials required. Additionally, operating HPLC instruments necessitates skilled personnel with the necessary expertise. It is also worth noting that HPLC may not be suitable for analyzing all types of compounds and mixtures. Furthermore, it may have limitations in detecting low levels of impurities or degradants, which could affect the accuracy of the analysis. In the absence of official methods, alternate methods serve as valuable alternatives, and HPLC is a reliable tool for assessing the quality and purity of products. However, it is crucial to carefully evaluate the advantages and limitations of utilizing these methods to ensure the most appropriate approach is chosen for each specific

situation. This consideration ensures accurate and reliable analysis while optimizing resource utilization and maintaining product quality standards.

Method validation

Method validation is an essential and fundamental process utilized to confirm the appropriateness and effectiveness of an analytical procedure for its intended use. Its primary objective is to ensure the quality, reliability, and consistency of analytical data, which in turn contribute to the overall reliability and accuracy of the analysis. The results obtained from the method validation process play a crucial role in assessing the suitability of the method and its applications. Method validation is an integral component of analytical practice, but it can vary depending on the specific method and its intended applications. The validation process is performed to establish and demonstrate key characteristics of the method, such as specificity, accuracy, precision, and reliability. It aims to ensure that the method is free from interferences and can accurately detect and quantify the analyte of interest at the required levels. The method validation process involves a series of well-defined steps. These steps include defining the validation characteristics, which outline the parameters to be evaluated, such as specificity, accuracy, precision, linearity, range, and the limit of detection and quantification. Furthermore, it entails evaluating the robustness and ruggedness of the method, which assesses the method's ability to withstand variations in experimental conditions and external factors. Each step in the validation process is crucial to optimize and validate the method for its intended use. The process must be carefully designed, meticulously executed, and well-documented to ensure that the results obtained are reliable and can be used to support the quality and safety of the product being analyzed. To achieve this, a comprehensive validation protocol must be established, clearly defining all relevant parameters, acceptance criteria, and procedures for evaluating the results. The protocol serves as a guide throughout the validation process, ensuring consistency, accuracy, and completeness of the data obtained. Method validation is an indispensable process in analytical practice. It plays a vital role in ensuring the quality, reliability, and accuracy of analytical data. By carefully designing and executing the validation process, analysts can establish the suitability of the method and generate reliable results that support the overall quality and safety of the analyzed product.

Significance of process validation

Process validation is a crucial undertaking that involves thoroughly examining the data collected during the design and manufacturing stages of a product. The primary goal is to ensure that the process has the capability to consistently produce products that adhere to predetermined standards. This meticulous process holds immense importance in guaranteeing the safety and quality of drug products and forms an integral part of the overall quality assurance system. The underlying principle of quality assurance is to ensure that any drug product manufactured is suitable for its intended use. Process validation serves as a means to provide assurance that the manufacturing process adheres to specific standards and requirements. It ensures that the process itself is reliable, consistent, and possesses the ability to consistently produce products that meet the desired specifications. The process of validation involves several key steps. Initially, critical process

parameters are identified, which are essential variables that directly influence the product's quality attributes. Subsequently, appropriate acceptance criteria are established, serving as benchmarks against which the product's performance will be evaluated. Finally, a comprehensive plan is developed to monitor and control the process throughout its lifecycle, ensuring on-going adherence to the predetermined standards. Within the pharmaceutical industry, process validation assumes even greater significance due to the stringent regulations and high-quality standards in place for drug products. The validation process plays a pivotal role in confirming that the manufacturing process is capable of consistently producing products that meet the required safety and quality standards. Moreover, it serves as an opportunity to identify any potential issues or risks associated with the manufacturing process and enable the implementation of appropriate corrective measures to mitigate these risks effectively. The validation of a process is a critical aspect of ensuring the safety and quality of drug products. It acts as a cornerstone of the quality assurance system, guaranteeing that the manufacturing process is robust, consistent, and capable of producing products that meet the predetermined standards. By conducting thorough process validation, organizations can instil confidence in the reliability and quality of their products, thereby safeguarding public health and well-being.

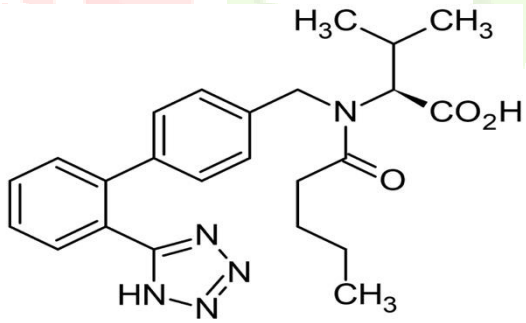
MATERIALS AND METHOD

DRUG PROFILE

VALSARTAN

Name: Valsartan

STRUCTURE



Description: Valsartan is classified as an angiotensin receptor blocker, which falls under a category of medications. Its primary mechanism of action involves the relaxation of blood vessels, thereby promoting smoother blood flow. By effectively lowering high blood pressure, Valsartan helps to mitigate the risks associated with cardiovascular complications such as heart attacks, kidney problems, and strokes.

Chemical formula: $C_{24}H_{29}N_5O_3$

Molecular weight: 435.5g/mol

IUPAC Name: (2S)-3-methyl-2-[pentanoyl-[[4-[2-(2H-tetrazol-5 yl)phenyl]phenyl]methyl]amino]butanoic acid

Categories: Angiotensin II receptor blocker

Solubility: soluble in ethanol, DMSO and dimethyl formamide at 30 mg/mL

Pharmacology Class: Anti-hypertensive drug

Mechanism of action: Through its targeted mechanism of action, valsartan acts to block the binding of angiotensin II to the AT1 receptor found in various tissues, including vascular smooth muscle and the adrenal gland. By doing so, it effectively impedes the actions triggered by angiotensin II, which include the release of aldosterone and constriction of blood vessels (vasoconstriction).

Melting point: 116-117 °C

Log P: 1.499

pKa: 3.6

Chemicals and the Reagents

Working standards for valsartan were supplied by Greensmed lab. The pill dosage forms used for analysis were obtained from the local market in Malappuram, specifically Valent 40 mg tablets manufactured by Lupin Laboratories. The amount of powder required for analysis was determined based on the labelled claim and the average weight of the tablets.

To prepare the necessary solutions, Merck supplied HPLC grade water and acetonitrile, which are of high purity and suitable for HPLC analysis. NICE, on the other hand, provided sodium dihydrogen orthophosphates and orthophosphoric acid of analytical reagent (AR) grade. These materials were utilized for the preparation of phosphate buffer, which is essential for the analytical process.

Buffer preparation

To prepare the phosphate buffer solution, start by taking a 1L volumetric flask. Precisely measure 1.0 gram of sodium dihydrogen orthophosphate and add it to the flask. Next, pour approximately 750 ml of HPLC grade water into the flask. Utilize a sonicator to degas the solution for a few minutes. Finally, complete the volume in the flask with HPLC water, ensuring it reaches the 1L mark. After preparing the solution, the pH needs adjustment. Dilute orthophosphoric acid is used to correct the pH to a value of 3.5. Carefully add the dilute orthophosphoric acid to achieve the desired pH level.

Standard preparation

Precisely measure 100 mg of valsartan and transfer it into a clean and dry 100 ml standard flask. Then, add 75 ml of buffer to the flask. To ensure thorough mixing and dissolution, sonicate the flask for a period of 45 minutes. The standard flasks are subsequently filled with buffer to reach the final volume. For further analysis, extract 1 ml of the prepared stock solution and transfer it into a separate 100 ml standard flask. To achieve a concentration of 10 mcg/ml, make up the volume in the flask with buffer. This results in the desired solution concentration for subsequent testing and experimentation.

Sample preparation

To determine the appropriate amount of powder needed for analysis, the weight equivalent (100mg) is calculated based on the labelled claim and average weight of the formulation obtained from the local market. This calculated weight equivalent of the powder is then accurately weighed and transferred into separate

clean and dry standard flasks with a capacity of 100 ml. Next, the powder is dissolved in 75 ml of buffer solution. The solution is carefully prepared by adding additional buffer to reach a final volume of 100 ml in the flask. The contents of the flask are then subjected to filtration to remove any impurities or solid particles. To continue the analysis, 1 ml of the filtrate is carefully transferred into a separate clean and dry 100 ml standard flask. This volume of the filtrate is appropriately diluted to achieve a final composition of a 10 mcg/ml solution of the medication. This resulting solution is then ready for further testing and experimentation.

Chromatographic conditions

To establish the chromatographic conditions, a C18 analytical column with specific dimensions (5 micron - C18, 250x4.6mm) from Kinetex was utilized. The mobile phase consisted of a combination of phosphate buffer with a pH value of 3.5 and acetonitrile, mixed in a ratio of 60:40. Prior to being introduced into the HPLC system, the mobile phase was degassed using a Sonica ultrasonic sonicator to remove any trapped gases or bubbles. For each sample, a volume of 20 microliters was injected into the HPLC system. The flow rate of the mobile phase was set at a constant rate of 1 ml per minute to ensure optimal separation and analysis. A wavelength of 273 nm was selected for detection purposes. To maintain consistent column performance and accurate results, the column temperature was maintained at a constant 25°C throughout the analysis process. These established chromatographic conditions formed the basis for conducting the HPLC analysis in a reliable and reproducible manner.

Method development

Several trials were performed for the method development and the best peak with least fronting factor was found in the fourth trials with reaction time of 4.774

Table no 1

SL.No	Chromatographic Conditions	
1	Mode of separation	Isocratic
2	Mobile phase	Phosphate Buffer (pH 3.5) and Acetonitrile (60:40)
3	Column	Phenomenex (250 x 4.6mm, 5µ)
4	Flow rate	1.0 ml/min
5	Detection wave length	273 nm
6	Injection volume	20 µl
7	Column over temperature	Ambient
8	Run time	10 min

Fig.1 chromatogram showing the retention time for valsartan

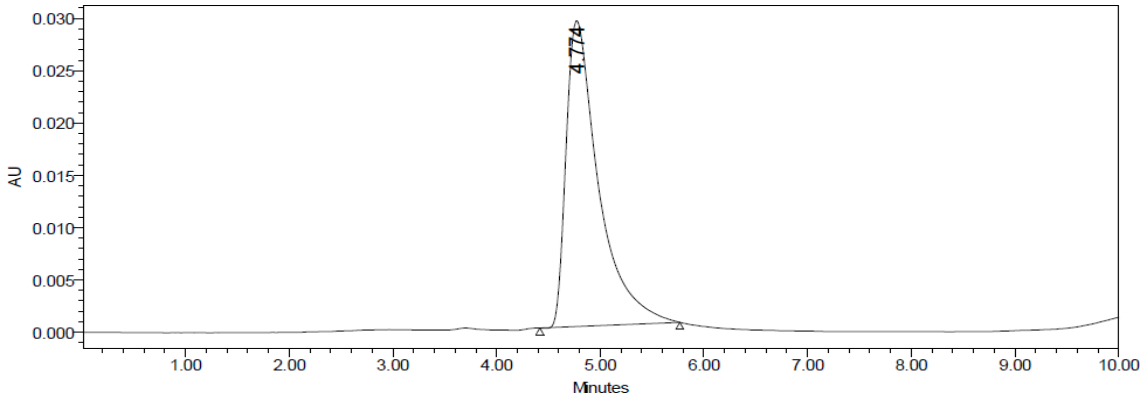


Fig 2 UV Spectrum

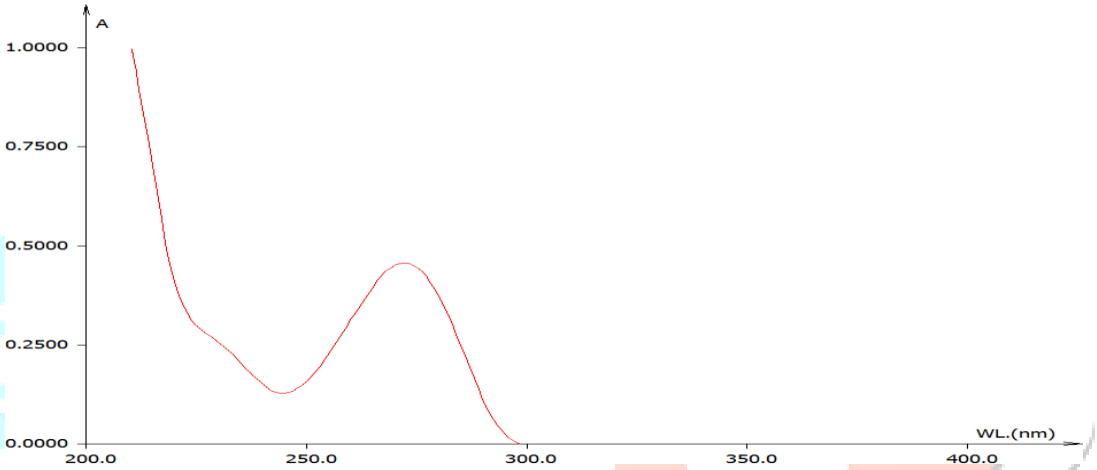
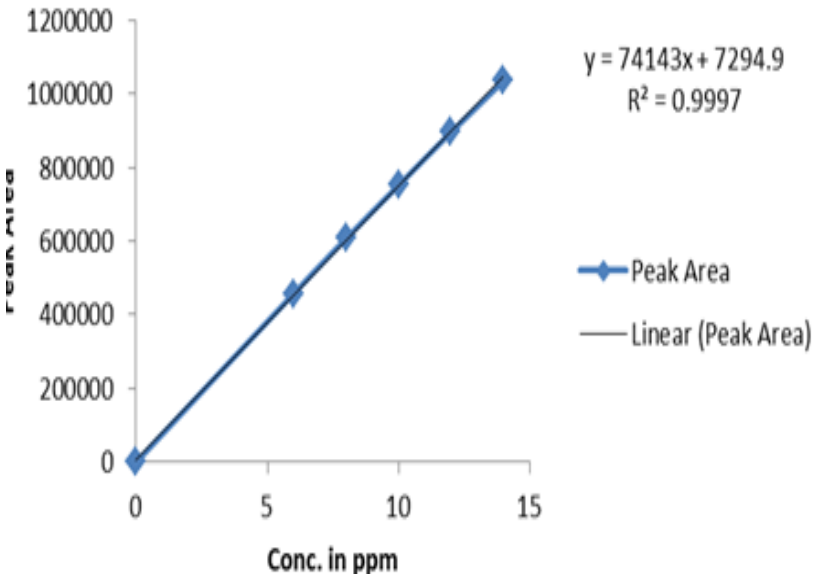


Fig 3 linearity graph



RESULTS AND DISCUSSION

Method validation

The validation process of the final test settings followed the guidelines and recommendations provided by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). These guidelines set forth the parameters that need to be evaluated to ensure the reliability and accuracy of the analytical method. The validation parameters, as outlined by the ICH recommendations, included specificity, accuracy, precision, linearity, detection limit, and quantitation limit. These parameters were thoroughly assessed to verify the performance and suitability of the analytical method. Specificity was evaluated to ensure that the method could accurately distinguish and quantify the target analyte in the presence of potential interferences or impurities. Accuracy was determined by comparing the measured values of the analyte with the true or expected values, providing an indication of the method's closeness to the actual value. Precision was assessed to determine the repeatability and reproducibility of the method. It examined the consistency of results when the same sample was analyzed multiple times (intra-day precision) or when different analysts or instruments were involved (inter-day precision). Linearity, on the other hand, assessed the relationship between the concentration of the analyte and its response. It ensured that the method exhibited a linear response within the desired concentration range, enabling accurate quantification of the analyte. The detection limit and quantitation limit were determined to establish the lowest concentration of the analyte that could be reliably detected and quantified by the method, respectively. By adhering to the ICH protocol, the validation process ensured that the final test settings were thoroughly evaluated and met the required criteria for specificity, accuracy, precision, linearity, and detection and quantitation limits. This rigorous validation approach provided confidence in the reliability and robustness of the analytical method.

System suitability

To ensure the adequacy and reliability of the chromatographic system used in HPLC processes, system suitability tests were performed. These tests play a crucial role in verifying that the system is suitable and capable of meeting the intended objectives. One of the important parameters evaluated during the system suitability test is the number of theoretical plates. The number of theoretical plates reflects the efficiency of the separation process, with higher values indicating better resolution and peak shape. In this case, the criterion for the system suitability test was set to have more than 2000 theoretical plates, which ensures a high level of separation efficiency. Another critical parameter assessed during the test is the tailing factor. The tailing factor provides information about the symmetry and shape of the chromatographic peak. A tailing factor value less than 2 is generally considered acceptable, indicating a symmetrical peak shape. The results of the system suitability tests were compiled and summarized in Table 2. This table provides an overview of the obtained values for the theoretical plates and tailing factor, indicating whether they fell within the acceptable limits. By conducting these system suitability tests and ensuring that the obtained results were within the acceptable limits, it was confirmed that the chromatographic system used in the HPLC processes

met the necessary requirements for efficient and reliable separation. This verification step is crucial in maintaining the quality and accuracy of the analytical results generated by the HPLC system.

Table no 2

Sl. No	Parameters	valsartan	Acceptable Criteria
1	Tailing Factor	1.421	Less than 2
2	Theoretical Plates	2945	Not less than 1500
3	Retention time	4.774	Less than 10
4	Area	747668	
5	% RSD	0.37	Less than 2%
6	HETP	93.33	
7	Resolution	1.417	

Linearity

Linearity studies play a significant role in assessing the relationship between the analytical measurements, such as absorbance diversity, and the concentration of the sample. These experiments are conducted to determine the linearity of the response generated by the analytical method. In the specific case of the active ingredient, linearity studies were performed to evaluate the relationship between its concentration and the corresponding response obtained from the analytical measurements. The study range for these experiments was set between 7 to 15 mcg/ml, covering a suitable concentration range for the active ingredient. The results of the linearity studies confirmed that the response exhibited a linear relationship within the specified concentration range. This means that as the concentration of the active ingredient increased, the corresponding response also increased in a consistent and proportional manner. The linearity observed in the study range of 7-15 mcg/ml provides confidence in the reliability and accuracy of the analytical method. It demonstrates that the method is capable of accurately quantifying the concentration of the active ingredient within this specific concentration range. By conducting linearity studies, the suitability and performance of the analytical method in measuring the active ingredient's concentration were assessed. This information is crucial in ensuring the accuracy and reliability of the analytical results and contributes to the overall quality assurance of the analysis process.

Specificity

Specificity refers to the capability of an analytical method to accurately detect and quantify the target analyte in the presence of other components that are typically found in the formulation. It ensures that the method can selectively identify and measure the analyte of interest without interference from other substances. In the case of the UFLC (Ultra-Fast Liquid Chromatography) study conducted for standard and sample preparations, the specificity of the method was assessed. The objective was to determine if any interferences, whether from diluents or the mobile phase, affected the retention time of the target analyte.

The study revealed that no interferences were observed, indicating that the method exhibited high specificity. The analyte's retention time remained consistent and unaffected by the presence of other components in the formulation or the mobile phase used in the analysis. This finding demonstrates that the method selectively detects and quantifies the target analyte without any significant interference from extraneous substances. The confirmation of specificity in the UFLC study provides confidence in the accuracy and reliability of the analytical method. It assures that the method can effectively distinguish the target analyte from other components present in the sample, ensuring the specificity and accuracy of the results obtained. By evaluating specificity, the method's suitability for detecting and quantifying the target analyte in the presence of potential interferences is established. This information is crucial in ensuring the reliability and validity of the analytical results, ultimately contributing to the overall quality control of the analysis process.

LOD and LOQ

The limit of detection (LOD) refers to the minimum concentration of a substance that can be reliably detected by a particular analytical procedure using specific instruments. It indicates the lowest concentration at which the analyte can be distinguished from background noise.

Similarly, the limit of quantification (LOQ) represents the lowest concentration of a substance that can be accurately and precisely measured using a specific analytical procedure with acceptable levels of precision, accuracy, and reliability. It establishes the minimum concentration at which the analyte can be quantitatively analyzed. During the analysis of valsartan, the drug used in the experiment, the LOD value was determined to be 0.92 mcg/ml. This means that the analytical method and instruments employed in the experiment were capable of reliably detecting valsartan at concentrations as low as 0.92 mcg/ml. Furthermore, the LOQ value for the AR (analytical reagent) grade was found to be 1.25 mcg/ml. This indicates that the analytical procedure and instruments used in the experiment could accurately and precisely quantify valsartan at concentrations equal to or higher than 1.25 mcg/ml. To ensure the validity and accuracy of the analysis, the signal-to-noise ratio for the analytical processes and instruments involved were rigorously monitored and validated. This quality control measure helps to assess the reliability and precision of the obtained results by ensuring that the analyte's signal is distinguishable from background noise. By determining the LOD and LOQ values for valsartan, the experiment establishes the sensitivity and capability of the analytical method and instruments to detect and quantify the drug accurately. These values provide critical information for future analyses and ensure the reliability and accuracy of the experimental results.

Robustness

Intentional modifications were implemented in the analytical approach, involving adjustments in the flow rate, mobile phase ratio, and temperature. However, these modifications did not result in noticeable variations in the obtained results. The findings remained within the specified range as defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). To assess the robustness of the method, specific conditions were established. These included flow rates of 0.9 ml/min and 1.1 ml/min, mobile phase concentrations of 50:50 and 70:30 for the buffer and acetonitrile, and temperature changes at 20°C and 30°C. Additionally, triplicate samples were injected to ensure accuracy and consistency. Under these robustness conditions, the system suitability parameters were evaluated. The obtained results demonstrated that the robustness modifications did not significantly impact the system suitability parameters. The relative standard deviation (RSD) remained within the acceptable limit. This indicates that the method developed using Ultra-Fast Liquid Chromatography (UFLC) was robust and capable of delivering reliable and consistent results even when deliberate variations were introduced. The evaluation of robustness provides important insights into the reliability and stability of the analytical method. By confirming that the method is not significantly affected by deliberate modifications, confidence is established in the method's ability to generate accurate and precise results in various operational conditions. This assessment contributes to the overall validation and quality control of the analytical procedure, ensuring its suitability for routine analysis and maintaining the integrity of the data obtained.

Accuracy

To assess the accuracy of the method, recovery analysis was conducted. This involved performing recovery tests at three different concentration levels: 75%, 100%, and 125% of the target analyte concentration present in the selected commercial forms. During the recovery tests, the percentage of analyte recovered at each concentration level was determined. Additionally, the mean percentage recovery for the analyte was calculated by averaging the recovery values obtained from the different concentration levels. To meet the accuracy criteria, the recovery of the analyte at each concentration level must fall within the allowed range of 2%. This range ensures that the method accurately measures the analyte's concentration in the commercial forms and provides reliable and precise results. By conducting the recovery analysis, the method's accuracy is thoroughly evaluated, as it determines how well the method can recover the target analyte from the samples. The investigation of recovery at different concentration levels provides insights into the method's ability to accurately quantify the analyte in a wide range of concentrations. Ensuring that the recovery values fall within the acceptable range is essential for establishing the accuracy and reliability of the method. It confirms that the method can consistently recover the analyte from the samples and accurately measure its concentration. The accuracy evaluation, through recovery analysis, adds a critical component to the overall validation process of the method, providing assurance that it can deliver accurate and reliable results when applied to real-world samples.

Accuracy Data of valsartan

SL. No.	Conc %	Peak Area	Amout Added mg	Amount Found mg	% Recovery	Mean Recovery %	SD	% RSD
1	75%	521341	3.75	3.70	98.66		0.92	0.2
2	100%	738020	5	5.02	100.4	99.58	0.82	0.12
3	125%	1046191	6.25	6.23	99.68		0..1	0.06

Precision

Precision refers to the measure of repeatability and consistency of procedures when conducted under typical operating conditions. It is commonly expressed as the relative standard deviation (%RSD). Precision assessments can be performed at different levels, namely, intraday and interday precisions. In the intraday precision study, multiple analyses of the same sample were conducted within a single day, while in the interday precision study, the analyses were conducted on different days. The %RSD value, which represents the variation between the results, was calculated for both intraday and interday precision data. The obtained precision data, as indicated by the %RSD values, were found to be less than 2%. This demonstrates that the proposed method exhibits precise and consistent performance. When the %RSD value is below 2%, it signifies that the method produces highly reproducible results with minimal variation. The achieved level of precision indicates that the proposed method can be relied upon to provide accurate and consistent measurements. The low %RSD values obtained from both intraday and interday precision studies confirm the method's ability to produce reliable results across different time points and replicate measurements. The assessment of precision is crucial in determining the method's reliability and the consistency of its results. When the precision is within an acceptable range, it assures that the method is capable of producing repeatable and consistent measurements, thus enhancing confidence in its analytical performance. The precise and consistent nature of the proposed method, as supported by the low %RSD values obtained from the intraday and interday precision studies, reinforces its suitability for accurate and reliable analysis in various practical applications.

Intraday and Inter day data of valsartan

		Intra day	Inter day
1	Retention Time	4.679	4.770
2	Avg. Peak Area	649070	587583
3	SD	13580	5766
4	% RSD	0.2	0.5

CONCLUSION

The stability-indicating test method presented in this study is characterized by its simplicity, speed, robustness, and reliability in the estimation of valsartan in both bulk and formulation samples. During the analysis, no interfering peaks were observed at the elution time, indicating the method's selectivity and specificity. To assess the suitability of the system, various system suitability parameters were evaluated. These parameters included linearity, precision, accuracy, resolution, theoretical plate, and retention time. The results obtained for the proposed method demonstrated that these parameters were appropriate and met the required criteria. Linearity, specifically, was established within the concentration range of 7-15 mcg/ml for the active ingredient, ensuring accurate and reliable quantification. Furthermore, the limit of detection (lod) for valsartan was determined to be 0.92 mcg/ml, indicating the lowest concentration that can be reliably detected by the analytical method. Similarly, the limit of quantification (loq) for the ar grade drug was found to be 1.25 mcg/ml, representing the lowest concentration that can be accurately quantified with acceptable precision, accuracy, and reliability. To assess the robustness of the developed method, various robustness conditions were tested. These conditions involved variations in flow rates (0.9 ml/min and 1.1 ml/min), mobile phase concentrations (50:50 and 70:30 for buffer and acetonitrile), and temperature changes (20^{o}c and 30^{o}c). triplicate samples were injected under these conditions, and the system suitability parameters were evaluated. The results demonstrated that the system suitability parameters were not significantly affected by these robustness conditions. the relative standard deviation (RSD), a measure of the variability of results, was within the acceptable limits. this indicates that the developed ultra-fast liquid chromatography (UFLC) method was robust and capable of providing consistent and reliable results even under different operating conditions. Overall, the stability-indicating test method developed in this study offers several advantages, including simplicity, rapidity, robustness, and reliability for the estimation of valsartan in bulk and formulation samples. the method exhibited selectivity, appropriate system suitability parameters, linearity within the desired concentration range, and low LOD and LOQ values. Additionally, the method's robustness was demonstrated by the negligible impact of variations in flow rates, mobile phase concentrations, and temperature on the system suitability parameters.

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CONFLICT OF INTREST

There is no conflict of interest in the work presented in this manuscript.

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