

Design, Development, Impurity Characterization for Comprehensive Impurity Profiling in Eprosartan Mesylate by a Robust LC-MS/MS-Q-TOF Method: Emphasis on EPR-I, EPR-II, and Regio-Isomers

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ABSTRACT

Background: Eprosartan mesylate along side its related impurities, EPR-I, EPR-II, and their regioisomers, were simultaneously identified and quantified utilizing a sensitive and selective LC-MS/MS technique in conjunction with high-resolution mass spectrometry employing a Q-TOF analyzer. **Materials and Methods:** A reversed-phase chromatographic separation was made on Hypersil BDS C18, (250 x 4.6 mm), 5 μ m at first, the composition of the mobile portion. A was 75% and B was 25%. Over 5 min, it was maintained constant. Subsequently, a linear gradient was applied from 5 to 19 min, increasing the proportion of B to 55%. Later was then held constant for 1 min before returning to the initial conditions of 75% A and 25% B, using ammonium acetate buffer and an acetonitrile with run time of 25 min, maintaining sampler cooler temperature at 5°C. Electrospray ionization (+ve) was deployed. Other source parameters were optimized as nebulizer gas pressure at 13 psi, curtain gas pressure at 12 psi, ion spray voltage at 4500 V, temperature at 325°C, focusing potential at 260 V, declustering potential at 55 V, and entrance potential at 10 V. A Q1 Multiple Scan type was used for data acquisition. **Results:** Analysis revealed the presence of Eprosartan at 3.12 min with an m/z of 425, EPR-I and its Regio isomer had similar molecular weights (m/z 335) but different retention times (16.56 and 12.81 min, respectively). Similarly, EPR-II and its Regio isomer shared a molecular weight (m/z 301 and 305, respectively) but had distinct retention times (11.88 and 11.03 min). As confirmed in compliance with ICH requirements, exhibiting exceptional specificity, EPR-I linear from LOQ-150% ($r^2=0.9988$), EPR-II linear from the LOQ-150% ($r^2=0.9985$), EPR-I regioisomer linear from the LOQ-150% ($r^2=0.9985$) demonstrated to be satisfactory by percentage recoveries at the LOQ level that fall between 98.0 and 103.0. The impurities had LOD and LOQ values of 0.06-0.1 ppm as well as 0.02-0.03 ppm, in each case. **Conclusion:** Aforesaid approach was successfully used to analyze Eprosartan Mesylate medicinal material and pharmaceutical formulations.

Keywords: EPR-I, EPR-II, Eprosartan, MS-Q-TOF, Regio isomer.

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INTRODUCTION

The growing rigor with which regulatory agencies monitor and manage the quality and purity of pharmaceuticals has piqued the interest of researchers all over the world in impurity profiling,^{1,2} and degradation studies of medicinal compounds.³⁻⁵ and pharmaceutical products. In addition, generic medications

and products are now required by law to undergo impurity profiling and a forced or stress degradation research. Two crucial considerations in pharmacological treatment are the medicine's efficacy and safety.^{6,7} Impurity and DP qualifying thresholds, reporting, and detection are covered in ICH guidelines Q3A and Q3B. One medication that can help lower blood pressure is Eprosartan mesylate, an ARB. Traditional methods have a few drawbacks, such as the fact that they are laborious and can become more so if numerous pollutants and DPs need to be detected in a single sample. The procedure becomes more time-consuming if the impurity or DPs produced are in minute quantities that cannot be enhanced. These factors have made hyphenated approaches the go-to option for identification and characterization in recent



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years.⁸⁻¹² particularly when impurities or DPs are present at trace levels. Eprosartan,¹³⁻²⁰ is commonly administered alone or in conjunction with other anti-hypertensive medicines. While several UV,²¹⁻²⁵ HPLC,²⁶⁻³³ methods have been developed for the analysis of Eprosartan-related impurities, and its relevant molecules in their tablet formulations, in human plasma and urine, these methods often rely on UV detection, which may not be sufficiently sensitive or specific for the detection of trace impurities. LC-MS/MS.³⁴⁻⁴⁷ offered superior sensitivity, selectivity, and specificity compared to traditional HPLC methods but couldn't clarify on sensitive detection of EPR-I, EPR-II, and their Regio isomers. By coupling LC-MS/MS with high-resolution mass spectrometry using a MS-Q-TOF analyzer, it is possible to detect and identify a wide range of impurities, including unknown impurities. The specific focus on EPR-I, EPR-II, and their Regio isomers is important as these have significant role on pharmacological and toxicological implications. It is feasible to guarantee that the pharmaceutical product satisfies strict quality standards by creating a sensitive and precise technique for the detection and measurement of these contaminants.

MATERIALS AND METHODS

Materials

EPR-I, EPR-II, EPR-I Regio isomer, EPR-II Regio isomer, and Eprosartan were sourced from Zydus Cadila Health Care Ltd in Secunderabad, India. LCMS-grade methanol, acetonitrile, and other required chemicals were supplied by the Merck Chemical Division in Mumbai. HPLC-grade water, purified using a Milli-Q water system, was used throughout the experiment. The chromatographic study took place out utilizing a Waters 2695 HPLC system, which was connected to a SCIEX QTRAP 5500 Mass Spectrometer and comprised of a high-speed autosampler, column oven, and degasser. Empower-2 software was utilized for data acquisition and analysis.

Methods

Primary Solution Preparation: Weighing and Dissolving: The following standards were carefully measured and put into individual 100 mL volumetric flasks EPR-I, EPR-II, EPR-I Regio isomer, and EPR-II Regio isomer. Totaling around 10 mg for each standard.

Dilution to Volume: A main solution with a concentration of 100 mg/L (or 100 ppm) was prepared by dissolving the standards and diluting them with the diluent until they reached the mark.

Secondary Dilution: First Dilution: A 100 mL volumetric flask was used to dilute the primary solution to the mark after 1.0 mL was pipetted into it. This gave a concentration of 1 mg/L (or 1 ppm).

To prepare the sample, about 300 mg equivalent was carefully weighed and transferred to a 10 mL volumetric flask. Diluting the sample to volume was the next step after dissolving it.

Evaluation of System

A blank (diluent), benchmark preparation, and sample setup six times into the chromatograph, recorded the chromatograms of each impurity, and computed the content using the following formula:

$$\text{EPR I ppm} = \text{AS/AT} \times \text{CS/CT} \times \text{P} \times 100$$

AT: Area counts of EPR-I peak.

AS: Average counts of EPR-I peak.

CS: Concentration of EPR-I.

CT: Concentration of sample.

P: The degree of purity of the EPR-I product.

Specificity

Eprosartan Mesylate and all impurity solutions were prepared independently in the diluent at a concentration of approximately 0.1 mg/mL during the solution preparation process.

LOD and LOQ

The Limit of Detection (LOD) and Limit of Quantification (LOQ) were determined by comparing the results from blank samples with those from samples with known analyte concentrations and calculating the signal-to-noise ratio. This allowed us to identify the lowest level (10 µg/mL) at which the analyte could be reliably identified.

Precision at LOQ

Six replicate influxes of a typical solution were examined in order to assess the accuracy at the LOQ level.

Linearity

By examining the solutions ranging from LOQ to 150% of the specified limit, the LC-MS/MS method's linearity was verified.

Accuracy

By employing the diluent, 10 mL of the 1 ppm solution was subsequently reduced to a total volume of 100 mL to achieve the desired concentration of 0.1 ppm. Intermediate Dilution: To reach a concentration of 0.06 ppm, 6 mL of the 1 ppm solution was diluted with 100 mL of the diluent.

RESULTS

Optimization of LC as well as Mass Situation

A Hypersil BDS C18 column (250 x 4.6 mm x 5 µm) was utilized. The material was detected with a UV detector set to 220 nm. The

mobile phase ran through the column at 1.0 mL/min, and the column oven was kept at 35°C to achieve proper separation and peak form. To prevent degradation, samples were injected at 30 µL and stored at 5°C in a sample cooler. The overall run time for the analysis was 25 min, and methanol was utilized as the diluent to effectively dissolve the materials. For the mass spectrometric analysis of Eprosartan and its impurities, utilizing an electrospray ionization (+ve). The nebulizer gas was set to a pressure of 13 psi, providing the necessary pressure to nebulize the sample into fine droplets. A curtain gas pressure of 12 psi was employed to prevent contamination of the ion source. Maintaining the ion spray voltage at 4500 volts is essential for the analyte's ionization. To facilitate the desolvation of the analyte ions, the ionization source's temperature was preset at 325°C. In order to guarantee that the ions were effectively focused into the mass analyzer, the focusing potential was adjusted to 260 volts. Before the ion stream entered the mass spectrometer, solvent molecules and any other neutral species were eliminated using a declustering potential tuned at 55 volts. Ions entered the mass analyzer more easily because the entrance potential fostered at 10 volts. The Q1 Multiple (Q1) scan type was used, which allowed for the selective identification and measurement of the relevant ions.

System suitability

Six replicate injections of a standard solution were evaluated in order to determine the system's appropriateness. The peak location for Eprosartan Mesylate impurities appears in Table 1.

Specificity

The Retention Time (RT) values and Mass Number (m/z) values as displayed in Table 2 were obtained for Eprosartan and impurities representative selective ion recorded chromatograms as shown in Figure1.

LOD and LOQ

The minimum level at which the analyte can be consistently recognized is established by assessing the signal-to-noise ratio, achieved through a comparison of results from samples with known analyte concentrations against those of blank samples. A tripartite solution was devised and examined to determine the quantitation threshold in relation to the detection limit. Table 1 presents the results that were achieved.

Precision at LOQ

Table 1 summarizes the peak area of Eprosartan Mesylate impurities.

Linearity

Results obtained are shown in Table 2 shown the line of best fit for peak area versus concentration for Eprosartan Mesylate impurities.

Accuracy at LOQ

By evaluating Eprosartan Mesylate spiked with its impurities at the LOQ level, the accuracy at LOQ was ascertained. Each solution has been created in three instances and examined separately. Table 2 reveals the percent of recuperation findings for the impurities.

Accuracy at specification level

By evaluating Eprosartan Mesylate spiked with its impurities at the specification level, the correctness was ascertained. Each solution was made in triple and examined separately. In Table 2 the proportion of recuperation results for impurities are exemplified.

Table 1: Summary of Analytical Performance of Eprosartan and Its Isomers.

Compound	Mean Peak Area (±SD)	r	LOD (µg/mL)	LOQ (µg/mL)	S/N (LOD)	S/N (LOQ)	% Recovery (LOQ)	% RSD
EPR I	306,983±6,677	2.18	0.03	0.10	3.5:1	10.4:1	100.0	2.00
EPR II	774,283±10,289	1.33	0.03	0.10	3.1:1	9.8:1	100.3	1.52
EPR Regio	501,950±11,424	2.28	0.02	0.06	3.3:1	10.1:1	100.0	1.67
EPR II Regio	3,048,667±97,852	3.21	0.03	0.10	3.5:1	9.9:1	102.0	0.98

Table 2: Chromatographic and Linearity Data of Eprosartan and Its Isomers.

Compound	RT (min)	m/z	Conc. (µg/mL)	Peak Area	% Recovery (Spec.)	%RSD (Spec.)
EPR I	16.56	335	0.1-3.0	15,120- 472,100	98.4 - 101.9	2.62
EPR II	11.88	301	0.1- 3.0	42,970- 1,261,000	Not tested at spec.	-
EPR I Regio	12.81	335	0.06-3.0	17,940- 886,100	99.1 - 102.1	1.57
EPR II Regio	11.03	305	0.1-3.0	132,100- 5,439,000	98.3 - 103.2	2.44
Eprosartan (parent)	3.12	425	-	-	-	-

DISCUSSION

Method development experiments

This included numerous essential procedures to improve analyte separation, resolution, and reproducibility. Initially, numerous columns and mobile phases were evaluated to determine an appropriate beginning place. The pH, flow rate, column temperature, and injection volume were then repeatedly optimized.

Validation

Specificity

Figure 1 depicts the retention time for EPR-I is 16.56 min with a m/z value of 335, whereas EPR-II is 11.88 min with a m/z value of 301. The EPR-I Regio isomer has a retention duration of 12.81 min and a m/z value of 335, the same as EPR-I. The EPR-II Regio isomer was identified with a retention duration of 11.03 min and a m/z value of 305. Eprosartan, the active medicinal ingredient, has the shortest retention time (3.12 min) and m/z value (425).

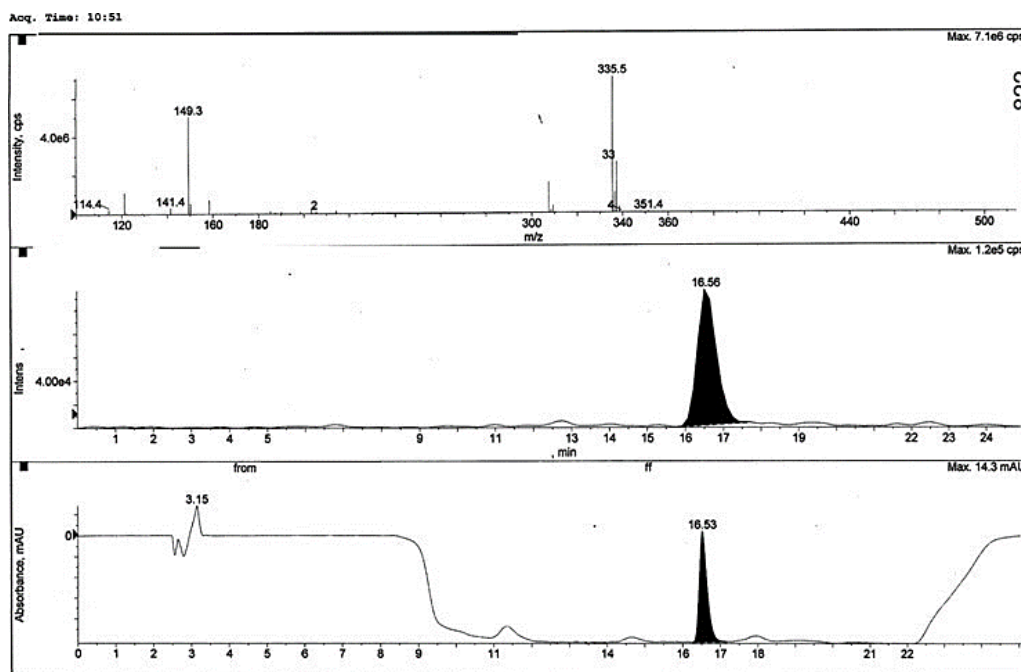


Figure 1: TIC of Eprosartan and its Isomers.

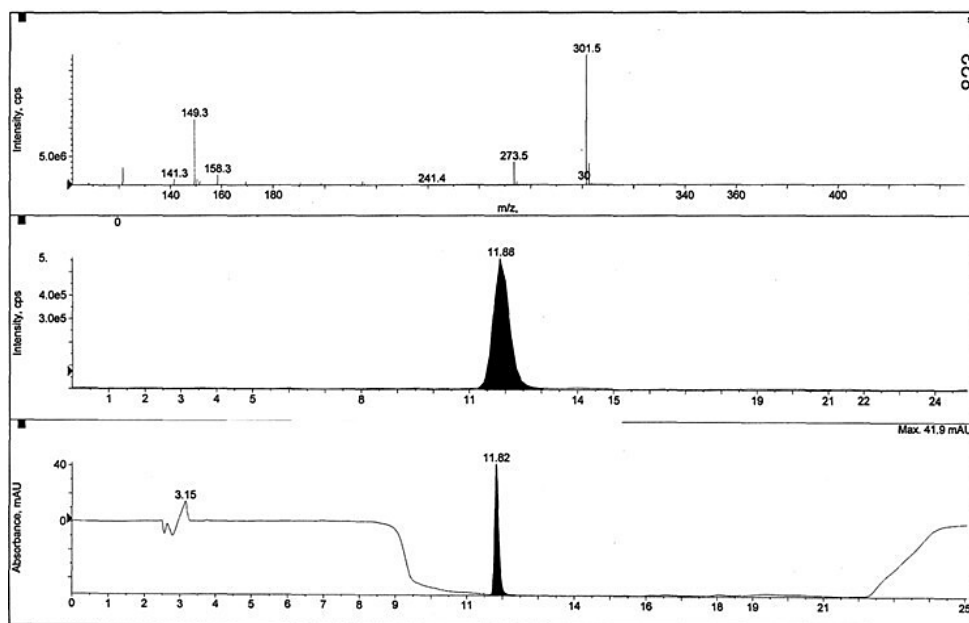


Figure 2 (a): TIC of Eprosartan and its Isomers (Accuracy Injection 1).

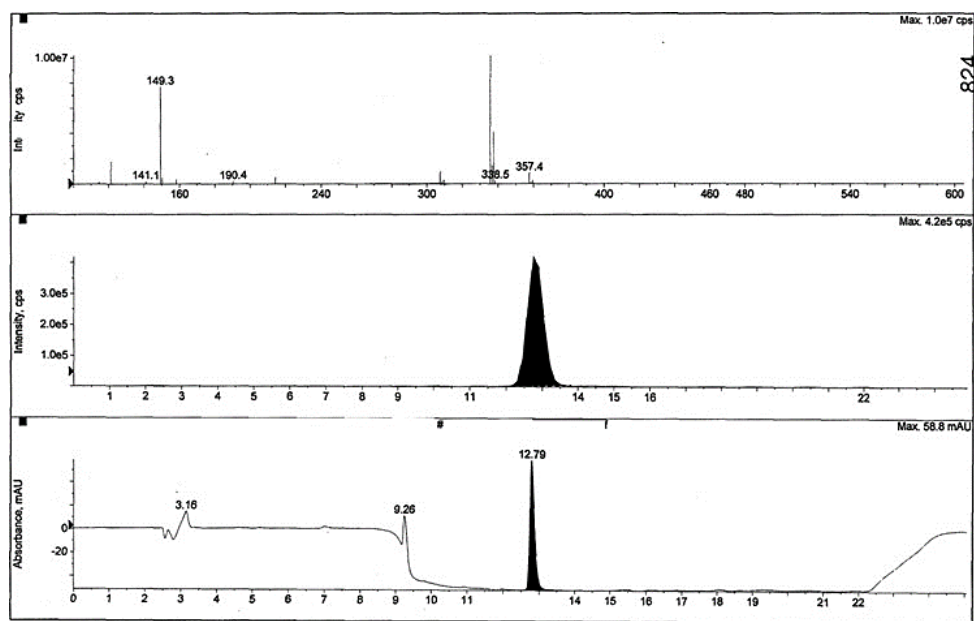


Figure 2 (b): TIC of Eprosartan and its Isomers (Accuracy Injection 2).

Precision

Study for the determination of EPR I, EPR I Regio isomer, and EPR II Regio isomer peak areas over six injections. The average peak areas for EPR I, EPR I Regio isomer, and EPR II Regio isomer were 306983, 774283, 501950, and 3048667, respectively. The % Relative Standard Deviation (%RSD) for EPR I, EPR I Regio isomer, and EPR II Regio isomer were calculated to be 2.18%, 1.33%, 2.28%, and 3.21%, respectively. These numbers show that the chromatographic approach has good precision.

LOD and LOQ

The provided data represents the peak areas and relative standard deviations for Eprosartan and its related impurities, including EPR-I, EPR-II, and their regioisomers. The data shows that the method exhibits good precision for all the analytes, with RSD values generally below 5%. This indicates that the method is reliable and reproducible, making it suitable for routine analysis.

Accuracy at LOQ

EPR-I's measured concentrations fell between 98.0% to 102.0% recovery with a %RSD of 2.00, implying suitable accuracy and precision per ICH Q2(R1). EPR-II also shown recoveries from 99.0% to 102.0%, therefore confirming the consistency of the method with a lowered %RSD of 1.52. Whereas the EPR-II regioisomer demonstrated even tighter recoveries (101.0% to 103.0%), the EPR-I regioisomer displayed recoveries between 98.3% and 101.7%; hence, the lowest %RSD of 0.98 shows exceptional precision and minimum variability. These results fit for routine analysis in line with regulatory filings since they confirm the accuracy and repeatability of the approach for all regioisomeric forms of EPR.

Accuracy at specification level

The accuracy evaluation at the specification level (1.8 ppm) for EPR-I, EPR-R, and EPR-II regioisomers as Figures 2a and 2b demonstrated the dependability of the method in measuring the analytes near their predicted concentration. EPR-I showed recoveries ranging from 96.8% to 101.9%, demonstrating reasonable accuracy with rather more variability with a %RSD of 2.62. EPR-R-evaluated across six replicates-showed tighter recoveries between 98.4% and 102.1%, exhibiting better consistency and method robustness with a lowered %RSD of 1.57. With a %RSD of 2.44, within reasonable limits according ICH Q2(R1), the recovery values for the EPR-II regioisomer ranged from 98.3% to 103.2%. The values verify the approach's capacity to consistently span duplicates and properly evaluate these regioisomers at specified doses. The method provides generally acceptable accuracy and repeatability for quantitative identification of EPR-related regioisomers, which is consequently appropriate for control and regulatory compliance.

Linearity

With related peak area responses obtained for EPR I, EPR II, EPR II regioisomer, and EPR I regioisomer, the linearity research was carried out throughout a concentration range of 0.1 to 3.0 (equal to 0.06 to 3.0). For every regioisomer, the acquired data amply show a proportional rise in response with increasing concentration, therefore supporting the linear relationship between concentration and detector response. The peak areas for EPR II and its regioisomer rose regularly from 15,120 and 42,970 at the lowest concentration to 472,100 and 1,261,000 correspondingly at the highest. Comparably, the EPR I regioisomer displayed a robust linear trend with peak areas ranging from 132,101 at 0.06 to 5,439,000 at 3.0. Excellent linearity indicated by this steady

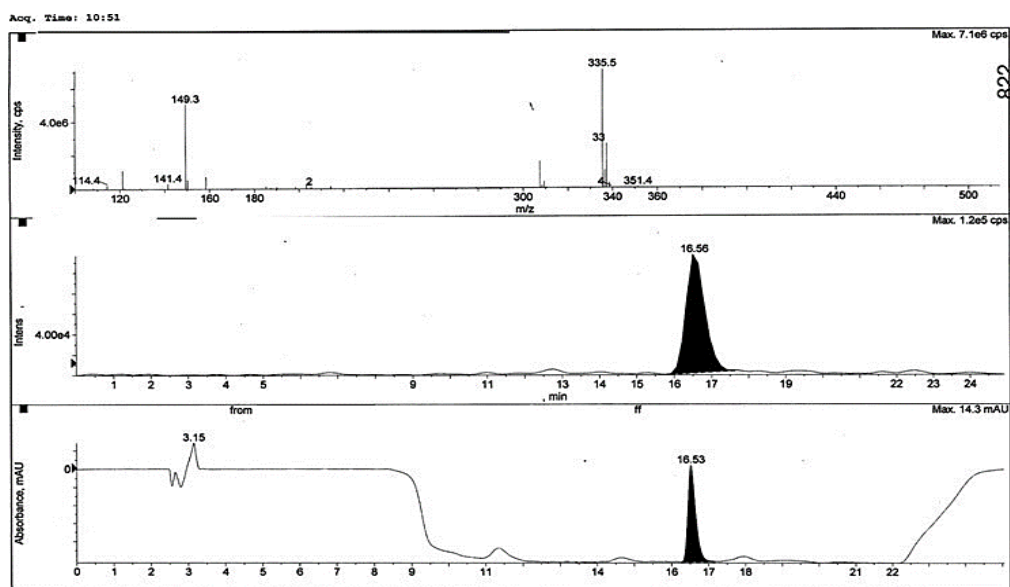


Figure 3: Regression analysis of EPRI, EPR II and EPR regioisomer.

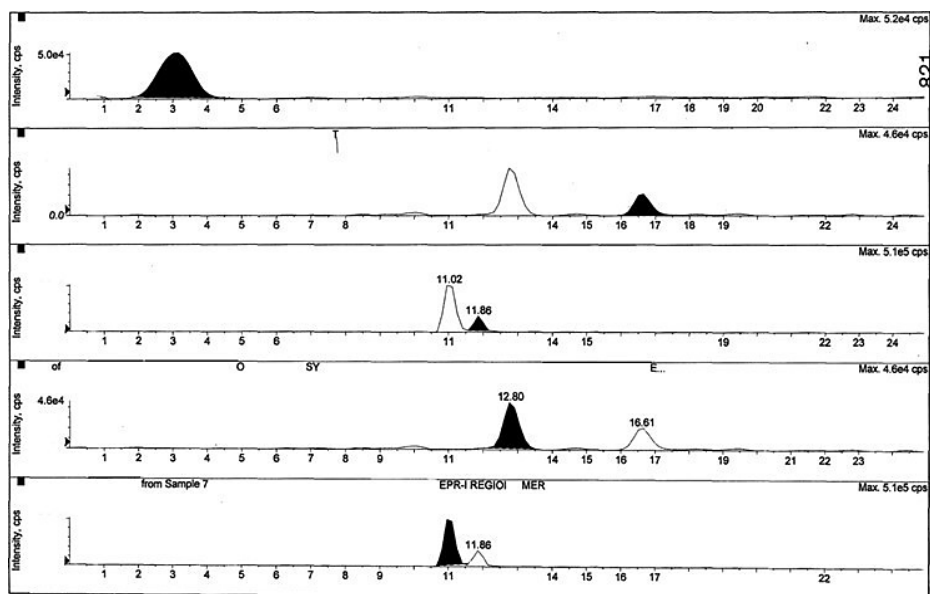


Figure 4: TIC of Eprosartan and its Isomers - Formulation.

rise over the range suggests the approach is able to consistently identify and quantify every regioisomer across the investigated range. EPR I regioisomer showed the best detector response among all the analytes at every concentration level, therefore indicating its stronger interaction with the detector or higher molar absorptivity. Plotting calibration curves and computing correlation coefficients (r^2 values) in Figure 3 would help one further confirm the linearity of response for every component; these values are expected to be ≥ 0.999 , thereby meeting criteria for standard ICH Q2(R1).

Application to formulation

The method demonstrated excellent effectiveness in detecting and analyzing impurities in Teveten (400 mg), the marketed

formulation of Eprosartan Mesylate as indicated in Figure 4. It accurately identified and quantified impurities such as EPR-I, EPR-II, and their regio-isomers, meeting the rigorous standards required for pharmaceutical quality control. With a detection limit as low as 0.02 $\mu\text{g/mL}$, recovery rates ranging from 98% to 103%, and precision under 5% RSD, the method was particularly useful for monitoring stability and detecting degradation products. Its well-optimized design, which combined efficient chromatographic separation with accurate mass analysis, ensured consistent batch quality and compliance with regulatory requirements.

CONCLUSION

The developed LC-MS/MS-Q-TOF method demonstrates exceptional sensitivity, selectivity, reliability for quantification of Eprosartan Mesylate and its related impurities, EPR-I, EPR-II, and their regioisomers. The method was optimized through extensive parameter adjustments, ensuring precise separation and accurate detection of impurities. The analytes' structural identities were validated by the retention durations and mass-to-charge ratios, whereas this method's capacity to identify residual contaminants is confirmed by the low LOD and LOQ values. Linearity, recovery rates within 98.0-103.0%, and %RSD values below 5% indicate the robustness, reproducibility of the approach. The safety and effectiveness of Eprosartan Mesylate formulations are guaranteed by this approach, which is ideal for regular batch monitoring and long-term evaluations.

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ABBREVIATIONS

mL: Millilitre; **g:** Gram; **mg:** Milligram; **µg:** Microgram; **NMT:** Not More Than; **RSD:** Relative Standard Deviation; **VF:** Volumetric flask; **mcg:** Microgram; **API:** Active Pharmaceutical Ingredient; **ARB:** Angiotensin II Receptor Blocker; **DPs:** Degradation products; **ESI:** Electrospray Ionization; **EPR-I:** Eprosartan Impurity I; **EPR-II:** Eprosartan impurity II; **HPLC:** High Performance Liquid Chromatography; **HRMS:** High Resolution Mass Spectrometry; **ICH:** International Council for Harmonisation; **LC-MS:** Liquid Chromatography Mass Spectrometry; **LC-MS/MS:** Liquid Chromatography Tandem Mass Spectrometry; **LOD:** Limit of Detection; **LOQ:** Limit of Quantification; **m/z:** Mass-to-Charge ratio; **ppm:** Parts per Million; **Q-TOF:** Quadrupole Time-of-Flight; **RSD:** Relative Standard deviation; **RT:** Retention Time; **UV:** Ultraviolet.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

A reliable and repeatable analytical method was developed and validated to identify and quantify Eprosartan and its impurities, including EPR-I, EPR-II, and its regioisomers. Several chromatographic parameters were fine-tuned throughout technique development to improve separation efficiency, resolution, and repeatability. The parameters were mobile phase composition, column type, pH, flow rate, temperature, and injection volume. Various retention periods and *m/z* values

showed specificity, including EPR-I at 16.56 min (*m/z* 335), EPR-II at 11.88 min (*m/z* 301), EPR-I regioisomer at 12.81 min (*m/z* 335), EPR-II at 11.03 min (*m/z* 305), and Eprosartan at 3.12 min. By precision testing with six injections, EPR-I, EPR-II, and Eprosartan had average peak areas of 306,983, 774,283, 501,950, and 3,048,667, respectively, with %RSD values of 2.18%, 1.33%, 2.28%, and 3.21%. This shows the outcomes were consistent. In LOD and LOQ tests, the method proved sensitive and repeatable with RSD values below 5%. From concentration units 0.1 to 3.0 (or 0.06 to 3.0 in other units), we sought for linearity. Peak areas of EPR-II, EPR-II regioisomer, and EPR-I rose linearly with concentration (from 15,120 to 472,100, 42,970 to 1,261,000, and 132,101 to 5,439,000). The results showed strong linearity, with an expected *r*² value of 0.999 or higher. EPR-I, EPR-II, EPR-II regioisomer, and EPR-I showed limited variability and remarkable precision at the limit of quantification (98.0%-102.0%, RSD 2.00%, 99.0%-102.0%, RSD 1.52%, 101.0%-103.0%, and 98.3%-101.7%, RSD 0.98%, respectively). The ICH Q2(R1) criteria were met when EPR-I, EPR-R, and EPR-II regioisomer recovery rates were between 96.8% and 101.9% (RSD 2.62%), 1.57%, and 2.44%, respectively. When applied to Teveten (Eprosartan Mesylate formulation), the method detected and quantified pollutants with a detection limit of 0.02 µg/mL, recovered 98%-103%, and had an RSD < 5%. This proves its applicability for rule-following, stability monitoring, and quality control.

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