A Review – HPLC Methods of Analysis for Cefixime

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Abstract- Cefixime is a member of the third generation of Cephalosporin antibiotics. It used on a wide scale in prescribed antibiotic drugs as anti-infection for Gram-positive and Gram-negative microorganisms. The present study aimed to develop an HPLC method of Cefixime analysis enjoyed highly linearity, repeatability, robustness, ruggedness, selectivity, rapidly, and economical to use. Cefeixime can be analysed using chromatographic, electrochemical, spectroscopic, and other techniques. These techniques assist in understanding crucial process variables and minimising the negative effects they have on precision and accuracy. To maintain high commercial product quality standards and to adhere to regulatory requirements, analytical method development is necessary. In various countries, regulatory organisations have created rules and practises for granting approval, authentication, and registration in response to the reference.

Keyword- Cefeixime, HPLC, Analytical methods.

Introduction-

Chemically, cefixime (CFX) is (6R,7R)-7- [[2-(2- amino-1,3-thiazol-4-yl)-2-(carboxymethoxyimino) acetyl] amino]-3-ethenyl-8-oxo-5-thia-1-azabicyclo [4.2.0] oct-2-ene-2-carboxylic acid [1]. It is used for treat gonorrhoea, otitis media, pharyngitis, lower respiratory tract infections including bronchitis, and urinary tract infections are only a few of the susceptible infections that are treated clinically with this drug [2]. It is widely utilised as an anti-infection agent for both Gram-positive and Gram-negative germs in prescribed antibiotic medications [3]. Due to its excellent safety profile and high efficacy, it is the best oral antibiotic for switch therapy. Furthermore, it is inexpensive in nature. It functions by eradicating germs, and because of its wide range of stability and antibacterial activity, it has analytical and therapeutic significance. Cefixime is used to stop the growth of bacteria that are resistant to antibiotics. Under various final products, it is introducing capsules and powder for oral suspension [4].

To determine Cefixime in various pharmaceutical dose forms, several analysis techniques have been established. These procedures use a variety of analysis techniques, such as high-performance liquid chromatography (HPLC) and microbiological approaches [5].

In bulk materials and various pharmaceutical dosage forms, Cefixime has been quantitatively analysed by spectrofluorimetric, spectrophotometry determination, colorimetry, and HPLC by capillary electrophoresis. HPLC-MS; mass spectrometric methods may have the maximum sensitivity, but the determination process is difficult to use. Voltametric determination [6]. One of the most practical, necessary, straight forward, and effective techniques for most qualitative and quantitative analyses is chromatographic separation.

Currently, HPLC is the most effective tool for excellent and optimal separation [7]. The lower concentration of Cefixime in various pharmaceutical dose forms was determined in the current investigation using an HPLC method with a photodiode array detector (PDA). It was discovered that the suggested analytical approach for Cefixime was exact, repeatable, linear, accurate, tough, robust, specific, selective, and economical [8].

Reviews on HPLC methods for Cefixime –

Bhinge et al., Cefixime and dicloxacillin have been measured at a single wavelength (225 nm) in order to assay using a straightforward, quick, and reliable RP-HPLC approach. The samples were isocratically eluted using a Capcell Pak C18 DDS5 column (4.6 mm 250 mm, 5 m particle size), with a mobile phase made up of 5 mM phosphate buffer, acetonitrile, and methanol (42:55:03, v/v/v), delivered at a flow rate of 1.0 mL min1. In the range of 0.5 to 25g mL-1, a satisfactory linear response was attained. The results showed that the LODs for CFX and CLX were 0.020 and 0.018g mL-1, respectively, while the LOQs were 0.315 and 0.205g mL-1, respectively. According to accepted standards, the method's linearity, precision, accuracy (recovery), selectivity, and robustness were quantitatively evaluated. The technique is straightforward, practical, and appropriate for evaluating cefixime and dicloxacillin in pharmaceutical formulations as well as in bulk form [9].

Dhara et al., The stability-indicating RP-HPLC method for the simultaneous measurement of Cefixime trihydrate and Levofloxacin hemihydrate in pharmaceutical dosage forms is described in the current work. The Shimadzu (LC20 AD) system with a PDA detector was used to create the suggested RP-HPLC method. Chromatographic separation was performed on a Phenomenex Luna C18 (250 x 4.6 mm x 5 mm) column at a flow rate of 1 mL/min. Methanol (45:55 v/v) and eluents were scanned using a PDA detector at 290 nm. The mobile phase contained 0.5% Glacial acetic acid in water that had its pH adjusted to 4.5 using ammonia solution. Levofloxacin hemihydrate and Cefixime trihydrate were shown to have retention times of 3.07 and 5.40 min, respectively. According to the ICH Q2R1 Guideline, the technique has been validated for linearity, accuracy and precision, LOD, LOQ, and system appropriateness. For Cefixime trihydrate and Levofloxacin hemihydrate, the verified lowest limits of detection were 1.0990 and 1.0008 g/mL, and the lowest limits of quantification were 3.331 and 3.032 g/mL, respectively. The average assay for Cefixime trihydrate and Levofloxacin hemihydrate was determined to be 98.5% and 100.4%, respectively. The medications were subjected to stress conditions like oxidation, acid and base hydrolysis, photo- and thermal degradation, and the stability indicating method was devised, and the deteriorated products created were successfully separated from the samples [10].

Madhuri et al., Cefixime and cloxacillin together have been measured using a straightforward and efficient RP-HPLC technique on C8 HiQsil. Phosphate buffer pH (3) column with acetonitrile as the mobile phase and a flow rate of 1 ml/min. 225 nm conveyed the detection. Cefixime had a retention duration of 2.120 and cloxacillin of 6.107. For cefixime trihydrate and cloxacillin sodium, the linear dynamic ranges were 2–12 g/ml (r2>0.999) and 5–30 g/ml (r2>0.995), respectively. For cefixime trihydrate and cloxacillin sodium, the mean percent recovery was found to be 100.314% and 100.830%, respectively. According to ICH guidelines, the method's linearity, precision, accuracy (recovery), selectivity, and robustness were quantitatively evaluated. The findings obtained demonstrate that the suggested RP-HPLC method is straightforward, quick, precise, accurate, and cost-effective, making it helpful for the

regular determination of cefixime trihydrate and cloxacillin sodium in bulk medication and in its tablet dosage form [11].

Nepal et al., For the simultaneous quantification of paediatric oral powder formulations comprising cefixime (CFX) and clavulanic acid (CVA), a novel reverse phase high-performance liquid chromatography (RP-HPLC) approach was created and validated. In this study, chromatographic separation was carried out on an analytical C18 (4.6 mm 25 cm), 5 m column using a mobile phase of methanol and water containing disodium hydrogen phosphate in a ratio of 20: 80 v/v (pH 5.5 adjusted with orthophosphoric acid) and flowing at a rate of 1.0 mL/min. The runtime and detecting wavelength were 220 nm and 15 min, respectively. Prior to fulfilling the requirements specified by the International Conference on Harmonisation (ICH), an analytical method was verified using the characteristics of specificity, linearity, and limit of detection. Accuracy, precision, resilience, and solution stability. (LOD), limit of quantitation (LOQ), and. The calibration curve was discovered to be linear between the concentration ranges of 0.024-0.036 mg/mL for CFX and CVA, respectively, and 0.032-0.048 mg/ml. The LOD and LOQ for CFX were also 0.0008 and 0.0025 g/mL, respectively. Additionally, a 30°C temperature was maintained for the column. LOD and LOQ of CVA were consequently 0.0021 and 0.0065 g/mL, respectively. Recovery trials were used to test the accuracy of the optimised approach. The mean recovery was found to be 98.96% for CFX and 99.05% for CVA at 100% spiked levels, respectively. The method is exact within the allowed range, and the %RSD of the precision was 2%, according to e repeatability testing for both standard and sample solutions. The results of both the CFX and CVA's linearity, accuracy, precision, robustness, LOD, and solution stability experiments were also within the permissible limit [12].

Shah et al., In this study, the simultaneous determination of cefixime (CEF) and linezolid (LNZ) using the Q-analysis or absorption ratio UV spectroscopic method and RP-HPLC method are developed and validated. For the test of Cefixime and Linezolid, respectively, the Q-analysis or absorption ratio technique amplitudes at 279 nm (Iso- absorptive point) and 257 nm (Linezolid's maximum) were chosen. For cefixime and linezolid, the linearity was discovered in the concentration ranges of 2–10 g/ml and 6–30 g/ml, respectively. Separating the components from the sample prior to the procedure is not necessary. The development and validation of the Reverse Phase High Performance Liquid Chromatographic technique. The mobile phase contained HPLC grade Water: Methanol: Acetonitrile (40:30:30% V/V/V), and the column was a Phenomenex Luna C18 column with a 250 mm x 4.6 mm, 5 m in isocratic mode. The flow was 1 ml/min, and effluents were observed at a wavelength of 279 nm. Cefixime and Linezolid both peaked on the chromatogram at 1.5 and 3.9 minutes of retention time, respectively. For cefixime and linezolid, the linearity was discovered in the concentration range of 0.01–15 g/ml and 0.03–45 g/ml, respectively. LOD values are determined to be 0.0037 g/ml for CEF and 0.0125 g/ml for LNZ, respectively. It is determined that the LOQs for CEF and LNZ are 0.0114 g/ml and 0.0373 g/ml, respectively. The current findings demonstrate that the suggested approaches can be used effectively to simultaneously determine the medication content in commercial formulations.

Remi et al., Drugs are typically analysed using high performance liquid chromatography using organic mobile phases like methanol, acetonitrile, among other dangerous and pricey chemicals. In the current investigation, hydrotropic solution was used as the mobile phase for the HPLC quantification of the medication Cefixime, which is weakly soluble in water. The

Agilent 1220 Infinity LC (G4288C) model, which consists of an Agilent 1220 Infinity LC pump, a Rhysodine injector (20-L loop), and a Variable Wavelength Detector, was used for the study. Agilent Eclipse Plus C18 (4.6 x 100mm) with 3.5 m particle size was the analytical column that was employed. The drug was detected at 290 nm at room temperature using an aqueous 6% sodium acetate (pH adjusted to 6.2 by acetic acid) at a flow rate of 1.0 mL/minute as the mobile phase. The approach Cefixime's retention period was discovered to be 2.34 minutes. In the concentration range of 40-240 g/mL, linearity was seen with a correlation coefficient of 0. 9999.Six replicate measurements were found to have a relative standard deviation percentage of 0.0055. This shows how accurate the suggested approach was. Within the bounds of linearity, recovery investigations were carried out at three distinct concentration levels. The average percentage in tablet dosage form was calculated and found to be 99.54%. As a result, the devised approach, which used a hydrotropic solution as the mobile phase, was unique, easy to use, exact, economical, safe, and suitable for the estimation of cefixime in pharmaceutical dosage forms.

Conclusion

This review has been emphasized mainly on the HPLC analytical methods used for the estimation of the cefixime in various medicinal drugs as well as in the bulk form of the drugs. Different dosage forms are containing a combination of cefixme. All the analytical methods developed are very sensitive, reliable, reproducible, precise and having a higher level of automation and sample throughput. The literature survey is done to collect the information of different analytical instrumental methods. Such data would get beneficial to develop a novel analytical method.

Competing Interests:

Authors report no conflict of interest concerning this review article.

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