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"VALIDATED ANALYTICAL APPROACHES FOR THE DETERMINATION OF CEFTAZIDIME IN BULK AND FORMULATED PRODUCTS: A SYSTEMATIC REVIEW"

[1]DR.CHANNAMMA G M, [2] JADHAV RAJASHRI DATTATRAY, [3]DR.KISHORE SINGH C, [4] DR.ASHOK KUMAR M.

[1]Professor, Department of Pharmaceutical Chemistry
[2]P G Research Scholar**,** Department of Pharmaceutical Chemistry
[3] Professor & HOD, Department of Pharmaceutical Chemistry
[4] Professor & Principal, Rajiv Memorial Education Society's College of Pharmacy Kalburagi - 585102**.** Karnataka, INDIA

ABSTRACT

Ceftazidime, a third-generation cephalosporin antibiotic, plays a critical role in the treatment of severe bacterial infections, particularly those caused by gram-negative organisms. Accurate and reliable estimation of Ceftazidime in both bulk drug and pharmaceutical formulations is essential for quality control and regulatory compliance. This systematic review presents a comprehensive analysis of various validated analytical methods developed for the quantification of Ceftazidime. Techniques such as UV-Visible spectrophotometry, high-performance liquid chromatography (HPLC), high-performance thin-layer chromatography (HPTLC), and liquid chromatography–mass spectrometry (LC-MS) are evaluated with respect to their specificity, sensitivity, precision, accuracy, and robustness. Emphasis is placed on the method validation parameters in accordance with ICH guidelines, including linearity, limit of detection (LOD), limit of quantitation (LOQ), and system suitability. The review also highlights the advantages and limitations of each technique and discusses emerging trends in analytical technology for Ceftazidime estimation. This article aims to provide researchers and pharmaceutical analysts with a consolidated reference for selecting suitable validated methods for routine analysis and quality assurance of Ceftazidime-containing formulations.

Keywords: Ceftazidime, Analytical Validation, Systematic Review, Formulated Products.

INTRODUCTION

Ceftazidime is a β-lactam antibiotic belonging to the third generation of Cephalosporins. It exhibits a broad spectrum of activity, particularly effective against Gram-negative bacteria, including *Pseudomonas aeruginosa*, and is frequently used in the management of serious infections such as pneumonia, urinary tract infections, skin infections, and septicemia. Due to its critical role in clinical therapy, especially in hospital settings, ensuring the quality, safety, and efficacy of ceftazidime in both bulk drug form and pharmaceutical formulations is of paramount importance. To achieve this, precise and validated analytical methods are essential for its accurate quantification during drug development, manufacturing, quality control, and stability studies.

Analytical methods play a central role in the pharmaceutical industry for the identification and quantification of active pharmaceutical ingredients (APIs), excipients and degradation products. The accuracy and reliability of these

methods directly influence the assessment of drug potency, purity, and shelf-life. Over the years, a wide range of analytical techniques have been developed and applied to determine Ceftazidime concentrations in various matrices, including bulk drug substances, injectable solutions, powders for reconstitution, and other formulated dosage forms. These methods vary in complexity, sensitivity, specificity, and applicability, depending on the analytical context and regulatory requirements.

High-performance liquid chromatography (HPLC) remains one of the most commonly used and validated techniques for the determination of Ceftazidime due to its high precision, reproducibility, and ability to separate Ceftazidime from its potential impurities and degradation products. Other chromatographic techniques, such as ultra-performance liquid chromatography (UPLC) and thin-layer chromatography (TLC), have also been employed. In addition, spectrophotometric methods, including UV-visible and derivative spectroscopy, offer relatively simple and cost-effective alternatives, particularly in settings where advanced chromatographic equipment is not available. Furthermore, electrochemical techniques and capillary electrophoresis have emerged as promising tools, offering high sensitivity and specificity with minimal sample preparation.

Method validation is a critical aspect of any analytical approach, ensuring that the method is suitable for its intended purpose. According to guidelines provided by regulatory authorities such as the International Council for Harmonisation (ICH), United States Pharmacopeia (USP), and the European Medicines Agency (EMA), analytical methods must be validated for parameters such as accuracy, precision, linearity, specificity, limit of detection (LOD), limit of quantitation (LOQ), robustness, and system suitability. Proper validation guarantees the reliability of the results generated and ensures compliance with regulatory standards during drug development and approval processes.

Despite the wealth of analytical methods available in the literature, there exists a need for a comprehensive and systematic evaluation of these techniques to guide researchers, analysts, and regulatory professionals in selecting the most appropriate and effective method for Ceftazidime analysis. A systematic review provides an organized synthesis of the available validated analytical methods, highlighting their operational principles, validation parameters, advantages, limitations, and potential applications.

This systematic review aims to collect, analyze, and summarize the validated analytical methodologies reported in peer-reviewed scientific literature for the determination of Ceftazidime in bulk and formulated pharmaceutical products. By examining the development trends and validation practices associated with these methods, this review seeks to identify gaps in current analytical practices, suggest areas for methodological improvement, and support the implementation of best practices in pharmaceutical analysis. Ultimately, this work contributes to the enhancement of drug quality assurance and regulatory compliance within the pharmaceutical industry.

LITERATURE REVIEW:

Andre`ia de Haro Moreno *et .al* ,[1] conducted a study on development of validation of the quantitative analysis of Ceftazidimein powder for injection by infrared spectroscopy. In this method calibration curve was obtained at 0.5 to 7mg and absorbance measurement of the band respective to centered aromatic ring at 1475-1600cm^{-1}**.**

A.R. Barenes,[2]conducted a study on determination of Ceftazidime and pyridine by HPLC: Application to a viscous eye drop formulation. The procedure is based on analysing aseptically prepared viscous Ceftazidime eye drop formulation. The maintained chromatographic conditions are spherisorb 5µm hexyl column. Mobile phase Acetonitrile, aqueous Ammonium acetate 0.05M in the ratio of 7:93. Flow rate is maintained as 2ml/min and wavelength is observed at 254nm.

Andre`iade, HaroMoreno *et al.*[3]conducted a study on spectrophotometric determination of Ceftazidime in pharmaceutical preparation s using Neocuproin as a complexing agent. This method was applied to the drug in an acidic medium, leads to theformation of yellow ternary complex in citrate buffer solution, maintaining pH and absorbance measurement at 4.2 and 454nm respectively. Beer's law is obeyed in the range of 15.0-40µg/ml.

S.D. Hanes, *et al.* [4] conducted a study on alternative method for determination of Ceftazidime in plasma by HPLC. In this first method involves solid phase extraction followed by ion pairing reverse phase chromatography. The peak height was determined at the concentration range of 1-200µg/ml.

Moreno *et al;*[5] conducted a study on comparison of high performance liquid chromatography and three titrimetric methods for the determination of Ceftazidime in pharmaceutical formulations. This procedure consist of mainly three different assays which isused for testing quality of Ceftazidime in commercial formulations [or] marketed products, which are further developed and compared with non-aqueous, acidimitric and iodometric methods conducted a study on development of new high performance liquid chromatographic method for the determination of Ceftazidime. This method describes accurate, rapid and sensitive HPLC method and validation for the determination of Ceftazidime in pharmaceuticals. The following are the maintained conditions for reverse phase chromatography: HPLC separation- waters C18 [WAT 054272; Milford, MA] column with methanol water[70+30, V/V]**,** flow rate of mobile phase : 1.0ml/min effluentrate: 245nm**.** linear calibration curve –50.0 to300.0g/ml

Basavaraj Hiremath , *et al.*[6] conducted a study on development and validation of spectrophotometric methods for determination of Ceftazidime in pharmaceutical dosage forms. In this procedure, two methods were developed. In the first method, MBTH reagent is made to react with Ceftazidime in the presence of ferric chloride in an acidic medium, the formed complex absorbs visible radiation at 628nm. In the second method, reaction between N-(1-naphthyl)ethylenediamine Dihydrochloride(NEDA) and diazotised drug to yield a purple coloured product, which is absorbed at 567nm.

Dell D, *et al.* [7] reported a high-performance liquid chromatographic method is described for the analysis of the anti-bacterial agent Ceftazidime in physiological fluids. Plasma or serum samples were mixed with chloroform--acetone to remove proteins and most lipid material. The aqueous phase was then freeze-dried, reconstituted in mobile phase and chromatographed on a reversed-phase column using UV detection at 262 nm. Urine was analysed directly after centrifugation to remove particulate matter. Two additional metabolites, which are lactones in which the β-lactam ring has been opened, could be separated by this method.

Yost RL, *et al.* [8] reported a reversed-phase high-performance liquid chromatographic assay for the simultaneous determination of Ceftazidime and its metabolite Ceftazidime in plasma and urine was developed. Plasma was deproteinized with small amounts of acetonitrile. After separation of the proteins the supernatant was extracted with a mixture of chloroform and 1-butanol. A phase separation was obtained leaving the cephalosporin and its metabolite in the aqueous part and extracting most of the interfering endogenous material. The aqueous phase was injected directly into the chromatograph. The assay was applied to study the pharmacokinetics of Ceftazidime and its metabolite in a healthy volunteer. In a similar way this deproteinization and extraction method was also applied to assay for Ceftazidime, Cephalexin, Cephazolin and Cefoxitin.

SandellAB, *et al.* [9] reported a simple, accurate and precise isocratic reversed-phase high performance liquid of a new cephalosporin in human serum and urine. Mobile phase was prepared by combining 170ml of Acetonitrile, 1.36g of monobasic sodium phosphate, 2ml of 85% phosphoric acid and 828ml of distilled water. Mobile phase B (used for urine assay) was prepared by combining 200ml of Acetonitrile, 1.36g of monobasic sodium phosphate, 2ml of 85% phosphoric acid and 798ml of distilled water at pH2.7 with flow rate of 2.0ml/min.

Okamoto Y, *et al.* [10] reported hydrolytic degradation products of Ceftazidime were studied in acidic (pH 1), neutral (pH 6) and basic (pH 9) solutions. Seven major degradation products were isolated by preparative and/or high-performance liquid chromatography and characterized by UV, IR, ^{1}H-NMR and mass spectra. To clarify degradation pathways in each pH solution, kinetic and product analyses during hydrolysis of Cefdinir were carried out along with the follow up reaction of representative degradation products. Cefdinir was shown to degrade via two major degradation routes: β-lactam ring-opening and pH-dependent isomerizations (lactonization, epimerization at C-6 or C-7, syn-anti isomerization of N-oximefunction).

Beckett AH, *et al.* [11] reported selective HPLC method is described for the determination of Ceftazidime levels in plasma and sinus mucosa. Sample preparation included solid-phase extraction with a C8 cartridge. Cefpodoxime and Cefaclor (internal standard) were eluted with methanol and analyzed on an optimised system consisting of a C18 stationary phase and a ternary mobile phase (0.05 M acetate buffer pH 3.8-methanol-acetonitrile, 87:103, v/v) monitored at 235 nm. Linearity and both between-and within-day reproducibility were assessed for plasma and sinus mucosa samples. The method was used to study the diffusion of Cefpodoxime in sinus mucosa.

KhopkarSM, *et al.* [12] reported the validation of the HPLC method used for the determination of Ceftazidime and its related substances was described. The developed method was specific and stability-indicating and provided a linear response with concentration. The system and method precision, expressed as relative standard deviations, were not greater than 1% and the reproducibility's within and between laboratories were acceptable for the assay method. The procedure can quantitate related substances greater than approximately 0.05% of the principle Cefdinir peak.

Kees F, *et al.* [13] reported in a cross-over study on twelve healthy volunteers Ceftazidime(CAS 87239-81-4) and Acetylcysteine (CAS 616-91-1) were evaluated for possible pharmacokinetic interactions. The narrow range of 90%confidence intervals for the quotient test/reference for Cmax and AUC indicate reliable bioavailability of Cefpodoxime proxetil independent of co-administered Acetylcysteine.

HanesSD, *et al.* [14]reported Ceftazidime was derivatised with 1,2-naphthoquinone-4-sulphonate (NQS), extracted into solid-phase cartridges (C18) and detected using a UV-visible detection system. Optimum conditions for this new procedure were: hydrogen carbonate-carbonate buffer, pH 10.5, 5-min reaction time at 25^{0}C and an NQS concentration of 7.1x10(-3) mol l(-1). The accuracy and the precision of the liquid-solid procedure were tested. The procedure was used to measure Cefotaxime in pharmaceutical and urine samples. The results obtained were contrasted with those reported for a HPLC method for urine samples. The generalized H-point standard additions method was used to measure Ceftazidime in urine samples.

Nanda RK, *et al.* [15] reported Cefotaxime sodium is a broad spectrum third generation antibiotic. It is obtained by reaction of 7-aminocephalosporanic acid (7-ACA) and S-(2-benzothiazolyl)2-amino-alpha-(methoxyimino)-4-thiazoleethanethioate. 2-Mercaptobenzothiazole is a by-product of this reaction. This technique is accurate, precise

(RSD = 0.4%), and has a sensitivity of 1.2%(differences in analytical response of 0.74 µg ml(-1) could be detected).Recovery experiments of Ceftazidime from reaction mixtures include 100% for all assayed concentrations. For these reasons, this technique is found valid for the intended purposes.

L Mohan Krishna, *et al.*[16] reported a HPTLC method for the determination of Ceftazidime, Cefixime and Ceftaxime, on a pre-coated silica gel HPTLC plates with concentrating zone (2.5x10cm) by developing mobile phase ethyl-acetone-methanol-water (5:2.5:2.5:1.5 v/v/v/v/). at 270nm.

Frank stttle, *et al.* [17]reported the determination of Terazosin in human plasma, using high performance liquid chromatography with fluorescence detection.

Ohannesian L, *et al.*.[18] reported a reversed-phase, isocratic high performance liquid chromatographic method with acid mobile phase can separate sulbactam and Cafoperazone within12 minutes. Column packed with Hypersil ODS2(250 mm x 4.6mm i.d., 5 µ) was manufactured by Dalian Elite company. Mobile phase is composed of water (adjusted to pH 4.0 with 1% phosphoric acid) and Acetonitrile (80:20, V/V). The detection was performed at 210 nm and the injection volume was 2 µ L. Ceftazidime and Sulbactam have good linearity in the ranges of 100 mg/L to 800 mg/L and 100 mg/L to 1,000 mg/L with the correlation coefficients of 0.9991 and 0.9997 respectively. This method is easily to be operated and can be applied for manufacturing and medicinal study.

Thomas M. *et al.* [19]reported a simple and sensitive HPLC method for the simultaneous determination of Ceftazidime (I) and desacetyl Cefotaxime (II)in human plasma and cerebrospinal fluid (CSF) is described. The assay involves deproteinisation and subsequent separation on a reversed-phase HPLC column, with ultraviolet detection at 262 nm. Retention times were 6.8 and 2.2 min for Ceftazidime and Desacetyl Cefotaxime respectively. Average recoveries for the analyses were 78% (I) and 88% (II) from both matrices. Linear responses were observed over a wide range (0.58-940 µg/ml for (I) in plasma, 0.80-55.8 µg/ml for (I) in CSF, 0.54-148 µg/ml for (II) in plasma and 0.50-36.0µg/ml for (II) in CSF)

Skoog, *et al.*.[20] reported a novel reversed-phase HPLC method was developed and validated for the assay of Ceftazidime and the limit of 4-epianhydrotetracycline hydrochloride impurity in tetracycline hydrochloride commercial bulk and pharmaceutical products. The method employed L1 (3 µm, 150 × 4.6 mm)columns, a mobile phase of 0.1% phosphoric acid and Acetonitrile at a flow rate of1.0 mL/min, and detection at 280 nm. The separation was performed in HPLC gradient mode. Forced degradation studies showed that tetracycline eluted as a spectrally pure peak and was well resolved from its degradation products.

Basavaiah K, *et al.*[21] reported electrochemical reduction behaviour of Ceftazidime, Cefixime (CF) and Cefpodoxime proxetil (CP) have been studied by using different voltammetric techniques in Britton-robinson buffer system. Two well defined cathode waves are observed for both the compounds in the entire pH range. Number of electrons transferred in the reduction process was calculated and the reduction mechanism is proposed. The results indicate that the process of both the compounds is irreversible and diffusion-controlled. A differential pulse voltammetric method has been developed for the determination of these drugs in pharmaceutical formulations and urine samples.

Sastry CSP, *et al.* [22] reported a high-performance liquid chromatographic method with ultraviolet (UV) detection was developed for measuring Cefotaxime in rat and human plasma. The method used direct injection of the plasma supernatant after deproteinization with 70% Perchloric acid. The speed, sensitivity, specificity and reproducibility of this method make it particularly suitable for the routine determination of Ceftazidime in human plasma. Moreover, only a relatively small sample plasma volume (100 µl) is required, allowing this method to be applied to samples taken from neonates.

Ehrlich M, *et al.* [23] reported a simple rapid and accurate spectrophotometric method for the determination of β-lactum drugs, Flucloxacillin and Dicloxacillin in pure form and different preparations. The absorption of Ceftazidime and Dicloxacillin are recorded in different pH values ranged from 2 to 12 and the curves at pH 2-12 are characterized by two absorption bands at 225 - 270 and 225 - 274nm. For Fluclox and Diclox respectively.

Ramakrishna R, *et al.*[24] reported accurate, precise, rapid and economical methods for the estimation of Cefixime and Ceftazidime in tablet dosage form. It is based on simultaneous equation and wavelengths selected for analysis were 290 nm Forcefixime and 312.0nm for Ornidazole.

Mohammad A, *et al.*[25] reported a RP-HPLC Method for the analysis of Ceftazidime in Bulk Material and in Capsule Consisting of a LC-10 AT VP pump, SPD-10AVP UV/ visible detector with column as bondapak C18 with mobile phase consist of Methanol: Buffer solution (sodium dihydrogen phosphate) in the ratio of 35:65 at a flow rate of 1ml/min.

Massart DL, *et al.*[26] reported new, simple, cheap, fast, accurate, sensitive and precise colorimetric methods that can be used for the determination of Ceftazidime. The developed methods were successfully applied to the determination of this drug in synthetic mixtures and commercially available tablets.

Nanda RK, *et al.* [27] reported validation is an act of proving that any procedure, process, equipment, material, activity or system performs as expected under given set of conditions and also give the required accuracy, precision,

sensitivity, ruggedness etc. When extended to an analytical procedure, depending upon the application, it means that a method works reproducibly, when carried out by same or different persons, in same or different laboratories, using different reagents, different equipments etc. In this review article discussed about the strategy and importance of validation of analytical methods.

Clayton.E, *et al.*[28] reported a simple, precise, accurate and sensitive reverse phase high liquid chromatographic method for simultaneous estimation of Ceftazidime and Erdosteine in combined capsules dosage form. Drugs were resolved on a HiQ Sil C8 column (25x4.6mm) utilizing mobile phase of Tetrabutylammonium hydroxide (0.1N) pH adjusted to 6.5 with Orthophosporic acid(10%aqueous) in a ratio of 2:1. Flow rate 1.0ml/min. at 254nm.

Venkataraman K, *et al.*[29] reported a reversed phase high performance liquid chromatographic for simultaneous estimation of Ceftazidime and Potassium clavanate in tablet dosage form by mobile phase consisting of 0.03M phosphate buffer and methanol in the ratio of 84:16 with wavelength is 220nm and flow rate is 1ml/min.

Amareswari S, *et al.*[30] reported a RP-HPLC method involving U.V detection and validated for the estimation of Ceftazidime and Cloxacillin in tablet dosage form using mobile phase Acetonitrile: Tetra-butyl ammonium hydroxide buffer in the ratio of 45:55 with pH adjusted to 4 with Orthophosphoric acid at 225nm at constant flow rate of 1ml/min.

PatelSA, *et al.*[31] reported development and validation of stability indicating HPLC method for the estimation of Ceftazidime related substances in tablets formulation.

Wang R, *et al.*[32] Development and validation of RP-HPLC method for the simultaneous estimation of Ceftazidime and Amlodipine in tablet dosage form.

Khandagle KS, *et al.*[33] reported analytical method development and validation for Ceftazidime as bulk drug and in pharmaceutical dosage forms by HPLC.

Sastry CSP, *et al.*[34] reported an isocratic reversed-phase UPLC method with UV detector has been developed for the determination of Methyl tsoylate , Ethyl tosylate and Isopropyl tosylate. These are potential genotoxic impurities and hence need to be controlled in Sorafenib tosylate. The analysts was performed using RRHD eclipse plus C18 UPLC column(50 x 2.1mm, 1.8um) as a stationary phase with column oven temperature 40ºC and UV detection at 264nm.. The method was optimized based on the peak shapes and resolution between Methyl tosylate , Ethyl tosylate , Propyl tosylate and Sorafenib tosylate.

Massart DL, *et al.*[35] reported comparative study of forced degradation behavior of Ceftazidime by UPLC and HPLC and development of validated stability indicating assay method according to ICH guidelines.

GlazkoAJ *et al.*.[36] reported impurity profiling has become an important phase of pharmaceutical research where both spectroscopic and chromatographic methods find applications. Proper peak shapes and satisfactory resolution with good retention times suggested the suitability of the method for impurity profiling .

Mohammad A, *et a.l*[37] reported a simple, short and stability-indicating reverse phase-ultra-performance liquid chromatography method was developed and validated for the quantitative determination of related impurities of Halobetasol propionate in Halobetasol propionate 0.05% cream formulation. The proposed method was developed on an ACQUITY UPLC™ BEH Phenyl (2.1 × 100 mm, 1.7 µm) column at 40°C with a mobile phase containing a gradient mixture of Potassium hydrogen phosphate buffer and Acetonitrile and methanol as modifiers with a run time of 13.0 min at a monitored wavelength of 242 nm. A simple preparative method and liquid chromatography–mass spectrometry-compatible UPLC method also were developed for the isolation and identification of impurities and degradation products.

Albert chivert, *et al.*.[38] reported development and validation of UV spectroscopic and HPTLC methods for the determination of Ceftazidime from tablet dosage form and low relative standard deviation and good % recovery values of both the methods showed that the developed methods were highly precise, accurate and free from interference present in formulation.

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