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AN OVERVIEW OF ANALYTICAL AND BIOANALYTICAL METHODS FOR ESTIMATION OF CEFACLOR ALONE AND IN THE FORM OF A MIXED DOSAGE

Diptimayee Jena[*1], Snigdha Rani Behera[1], Gowri Sankar Chintapalli[1], Satyam Kumar[1], Kirtimaya Mishra[1]

[1*]School of Pharmacy, ARKA JAIN University, Jamshedpur, Jharkhand, India.

ABSTRACT

This study offers a synthesis of already published analysis methods Cefaclor, either alone or in combination with other medications. Many spectroscopic techniques, including derivative and chromogenic approaches, are available. There is also a novel and improved chromatographic technique based on biological fluids and pharmaceutical formulations. There are a few LC-MS/MS and HPTLC procedures in addition to these two ways. The quality through design or professional method is employedin today's analytical research environment to acquire a better way for method validation. This brief review assignment might help an analyst determine the optimal way for developing and validating analytical procedures.

KEYWORDS

Cefaclor, Analysis, Analytical method development, HPLC and UV.

Author for Correspondence:

Diptimayee Jena,

School of Pharmacy,

ARKA JAIN University,

Jamshedpur, Jharkhand, India.

Email: diptijena72@gmail.com

INTRODUCTON

As a result of this discovery, a revolution in human health has occurred, drugs emerge on a daily basis. These medications will work best if they are pure and devoid of impurities. Novel chemical and instrumental procedures for generating impurity-free medications were developed at regular intervals. Impurities can arise at any point in the process, from bulk drug production to finished product packing and storage (degradation). The most likely source of impurities is during transit and storage. As a result, pollutants in these conditions must be identified and quantified. Analytical instrumentation and procedures are critical for detection and quantification[1].

Since it includes testing of bulk medications, intermediate pharmaceutical analysis is an important method for therapeutic process monitoring. Examples of drug materials include drug formulations, degradation products, chemically stable pharmaceuticals, and harmful components. Many diabetic individuals now benefit from polypharmacy. As a result, testing mixed formulations and biological sample analysis are critical to enhancing polypharmacy therapy quality control.

Antibiotics are drugs that cure bacterial illnesses in people and animals. They either kill or make it difficult for germs to thrive and multiply[2].

Carbapenems, like penicillins and cephalosporins, belong to the beta lactam class of antibiotics that kill bacteria by adhering to penicillin-binding proteins and preventing the development of bacterial cell walls[3]. Cephalosporins are antimicrobials that destroy bacteria by using their beta-lactam rings. The beta-lactam rings bind to the penicillin-binding protein and inhibit its normal action[4]. In short-term clinical trials, no higher incidence of acute pancreatitis was reported with Cefaclor, Cefadroxil, Cefazolin, Cefdinir, Cefditoren, Cefepime, Cefixime, Cefotaxime, Cefotetan, Cefoxitin, Cefpodoxime, Cefpodoxime, Cefpodoxime, Cefpodoxime, Cefpodoxime[5]. Cephalosporins class drugs include Cefaclor, cefadroxil, cefazolin, cefdinir, cefditoren, cefepime, cefixime, cefotaxime, cefotetan, cefoxitin, cefpodoxime, cefprozil. Detail about the Cephalosporins class drugs given in Table No.1.

Cefaclor

Cefaclor is one of the Cephalosporins class medications that is briefly mentioned in this publication.

Chemically, cefaclor (6R, 7R)-7-[(2R)-2-amino-2-phenylacetyl] amino-3-chloro-8-oxo-5-thia-1-azabicyclo [4.2.0] oct-2-ene-2-carboxylic acid (Figure No.1) is a carboxylic acid composed of -7-[(2R)-2-amino-2-phenylacetyl] amino-3-chloro-8. In adults and children 3 months of age and older, cefaclor injection is used to treat skin and abdominal (stomach area) infections caused by bacteria, as well as meningitis (infection of the membranes that protect the brain and spinal cord). Cefaclor belongs to a class of antibiotics known as cephalosporins. It acts by inhibiting bacterial growth. Cefaclor and other antibiotics will not treat a cold, flu, or other viral infection.

Several analytical methods based on UV, RP-HPLC, and LC-MS/MS were published for the pharmacokinetic assessment of Cefaclor phosphate in human, rat, and dog plasma and urine.

This review paper focuses on the analytical methods available for Cefaclor estimation, such as electrochemical methods, UV/VIS-spectrophotometric methods, HPLC/LC-MS, GC-MS, and CE/CE-MS. Table No.2 and Table No.3 cover the specifics of the past research.

Quality by design

To increase the quality of medications, several analytical procedures are available[20-21]. However, the Quality by Design strategy is now commonly utilised to improve the analytical procedure. Quality by design (QbD), as mentioned in ICH Q8[1], Q9, and Q2, is widely established for pharmaceutical development and manufacturing.

Benefits of Quality by Design Method

It aids in the creation of a reliable approach. Sources of variability can be better controlled according to the design arrangement. Method When a method is translated from the research level to the quality control department, the likelihood of success increases. This technique allows for the development of new procedures through continual improvement throughout the lifecycle[22].

Table No.1: Details of Cephalosporins class drugs

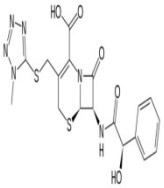
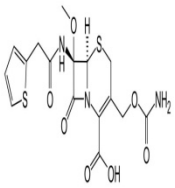
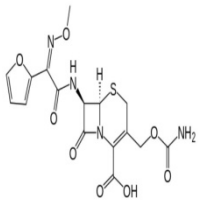
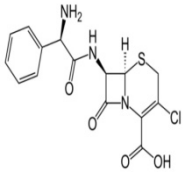
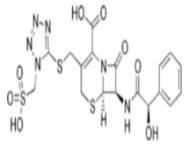
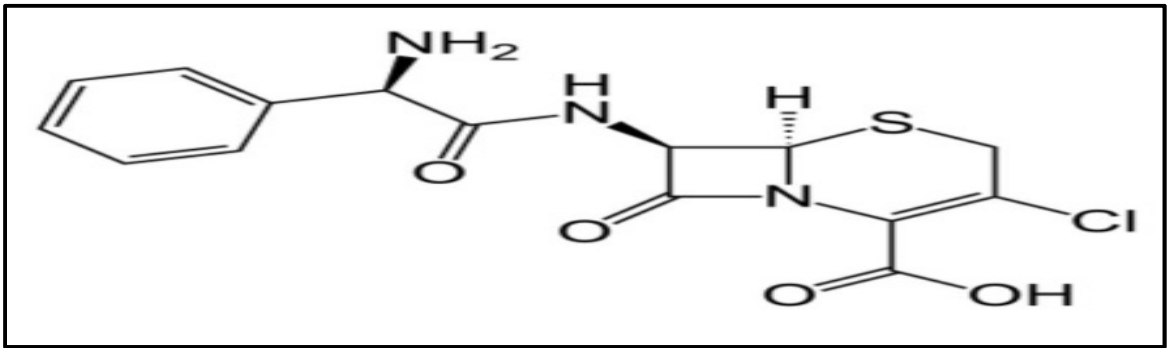
Drug	Sructure	IUPAC Name	Molecular Weight	Solubility
Cefamandole		(6R,7R)-7-{[(2R)-2-hydroxy-2-phenylacetyl]amino}- 3-[(1-methyltetrazol-5-yl)sulfanylmethyl]-8-oxo- 5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid	462.505g/mol	DMF: 30mg/ml DMSO: 30mg/ml PBS (pH 7.2): 10 mg/ml
Cefoxitin		(6R,7S)-3-(carbamoyloxymethyl)-7-methoxy-8-oxo-7-[(2-thiophen-2-ylacetyl)amino]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid	427.454g/mol	Cefoxitin is very soluble in water and slightly soluble in acetone. It is insoluble in chloroform and in ether, sparingly soluble in dimethylformamide, and soluble in methyl alcohol. The pH of a 10% aqueous solution is between 4.2 and 7.0 Sweetman (2003).
Cefuroxime		(6R,7R)-3-{[(Aminocarbonyl)oxy]methyl}-7-{[(2Z)-2-(2-furyl)-2-(methoxyimino)acetyl]amino}-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid	424.386g/mol	Cefuroxime is a white or almost white powder. The amorphous form is insoluble in water and in ether, slightly soluble in dehydrated alcohol, and freely soluble in acetone. It is also soluble in chloroform, in ethyl acetate, and in methyl alcohol.
Cefaclor		(6R,7R)-7-{[(2R)-2-amino-2-phenylacetyl]amino}- 3-chloro-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene- 2-carboxylic acid	367.808g/mol	Cefaclor is slightly soluble in water, practically insoluble in chloroform, in methyl alcohol, and in benzene. The pH of a 2.5% suspension in water is between 3.0 and 4.5.
Cefonicid		(6R,7R)-7-[(2R)-2-hydroxy-2-phenylacetyl)amino]-8-oxo-3-{[1-(sulfomethyl)tetrazol-5-yl]sulfanylmethyl}-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid	542.56g/mol	

Table No.2: Details about HPLC analytical method development

S.No	Stationary phase (column)	Mobile phase (with ratio)	Ph	Wavelength	Flow rate	Reference
1	C18 (4.6×250mm)	Acetonitrile: methanol: triethyal amine buffer (1:1:2 v/v)	7	260nm	0.6ml/min	6
2	C18 Knauer column	Triethylamine: methanol: acetonitrile: water (2:10:20:68) v/v%	-	264nm	1.0ml/min	7
3	Hypersil BDS C18 column (250mm×4.6mm)	Water: trimethylamine: methanol (78:10:22 v/v)	2.5	265nm	1.5ml/min	8
4	ODS Coolumn (4.6mm×250mm, 5µm particle)	50mM phosphate buffer (acetonitrile gradient form 2.25to 45%)	4	220nm	1.0ml/min	9
5	Lc-18-DB (250mm×4.6mm I.D.)	Methanol, THF, Aqueous component (16:4:80)	2.3	265nm	1.4ml/min	10
6	Diamonsil C18 Column (250×4.6mm, 5µm; Dikma, Beijing, China)	Water: trimethylamine: methanol (78:10:22 v/v)	≤4.5		0.55ml/min	11
7	Capillary column (15cm x 0.3mm i.d)	Deionized water/ Methanol/ acetic acid/ Glycerol (69:30:0.5:0.5, V/V)	5	262	4µl/min	12
8	ODS column (4.6mm x 250mm, 5-µm particles)	Methanol, THF, Aqueous component (16:4:80)	4.0	220nm	1.0ml/min	13
9	C18 HPLC, column 5-µm particles size, Lx1.D.25 CM x 4.6mm (Supelcosil)	Sodium 1-Pentane Sulfonate, water, triethyl amin, methanol	2.5±0.1	265nm	1.5ml/min	14
10	Supelcosil LC-18-DB (250mm x 4.6mm I.D)	Methanol, THF, Aqueous component (16:4:80)	2.3	265nm	1.4ml/min	15

Table No.3: Details for Spectroscopic method developments

S.No	Drug	Method	Description	Reference
1	Estimation of Cefaclor with stability studies	Spectroscopy method	Detection Wavelength: 262.4nm in distilled water Linearity range: 5-50µg/ml Co-relation Co-efficient: 0.9989 % Recovery range: 92.5-95.5% %RSD: ≤2%	16
2	Analysis of Cefaclor in novel chocolate-based camouflage capsules	UV detection	Detection Wavelength: 265nm Linearity range: (0.40mg/ml - 0.60mg/ml) Co-relation Co-efficient: 0.9976 % Recovery range: 74.9% RSD: 0.86	17
3	Area of under curve spectrophotometric method for estimination of cefaclor	Area under the curve method	Detection wavelength : 230-240nm Linearity range: 4-22 Regression Co-efficient: 0.9997 % Recovery range: 98.79% RSD: 0.794	18
4	Spectrophotometric determination of cefaclor pharmaceutical preparation	Spectrophotometric method	Detection wavelength : 340nm Linearity range: 252-270nm Co-relation Co-efficient : 0.05001 % Recovery range: 98.08± 0.20	19



(6R, 7R)-7-{[(2R)-2-amino-2-phenylacetyl] amino}-3-chloro-8-oxo-5-thia-1-azabicyclo [4.2.0] oct-2-ene- 2-carboxylic acid

Figure No.1: Chemical structure and IUPAC name of Cefaclor

CONCLUSION

This study reports on chromatographic and spectrophotometric methods that were developed and verified for the evaluation of Cefaclor. According to this review, various spectroscopic and chromatography techniques for Cefaclor are available for both the individual component and the combination, and it has also been concluded that the majority of the chromatographic methods have higher resolution due to a mobile phase containing phosphate buffer, methanol, and acetonitrile. It was discovered that the most commonly utilised formulation of Cefaclor was (ex. Ceclor). To get a good retention period with a chromatographic technique, the flow rate should be in the range of 0.8-1.5ml/min. Methanol is a common solvent for most spectroscopic techniques. As a result, all methods discovered to be simple, accurate, economical, precise, and reproducible. However, it was obvious from this research that existing approaches can be enhanced by employing the Design of Expert (DOE) technique, which will produce more accurate and exact results.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

BIBLIOGRAPHY

1. Siddiqui M R, AlOthman Z A, Rahman N. Analytical techniques in pharmaceutical analysis: A review, *Arabian Journal of Chemistry,* 10(1), 2017, 1409-1421.
2. Matthew, Hutchings A. Antibiotics: Past, present and future, *Current Opinion in Microbiology,* 51, 2019, 72-80.
3. Biljana A, Jill B, Ana C, Milan M, Nevena S, Predrag N. 16-membered macrolide antibiotics: A review, *Int J Antimicrob Agents,* 51(3), 2018, 283-298.
4. Palanisamy P, Gowdhaman K, Jaykar B, Margret C R. Formulation and evaluation of film coated tablets of azithromycin USP, *International Journal of Medicine and Pharmacy,* 1(1), 2013, 59-70.
5. Tilman C S. Gliptins, dipeptidyl peptidase-4 inhibitors, and risk of acute pancreatitis, *Pubmed,* 12(4), 2013, 545-557.
6. Shah J. Development and validation of HPLC method for simultaneous determination of Ceftriaxone and Cefaclor in commercial formulations and biological samples, *Jour of the Mex Che Soc,* 57(4), 2013, 314-320.
7. Mohammad A A. Comparision of HPLC and UV Spectro-photometric methods for the determination of Cefaclor Monohydrate in pharmaceutical dosages, *Med Chem,* 6(1), 2016, 19-22.
8. Mohamed M A, Ali A H, Ahmed M O. Validation and comparative In-Vitro dissolution studies of Cefaclor in their powder for oral suspension dosage forms, *Analytical Chemistry Letters,* 8(1), 2018, 88-103.
9. Lorenz L J, Bashore F N, Olsen B A. Determination of process-related impurities and degradation products in Cefaclor by high-performance liquid chromatography, *Journal of Chromatographic Science,* 30(6), 1992, 211-216.
10. Paul M K, Ronald L J, Gordon B. High-performance liquid chromatographic determination of loracarbef, a potential metabolite, cefaclor and cephalexin in human plasma, serum and urine, *Journal of Chromatography B: Biomedical Sciences and Applications,* 567(1), 1991, 129-139.
11. Naz S, Shoaib M H, Bashir L, Yousuf R I, Anjum F, Siddiqui F, Yaseen S. HPLC method development and validation for the determination of Cefaclor in human plasma, *Pak. J. Pharm. Sci,* 30(5), 2017, 1645-1649.
12. Ethiraj T, Revathi R, Chandru S. Method development and validation of spectroscopic method for content analysis of Cefaclor with stability studies, *Asian Journal of Pharmaceutical Research,* 9(2), 2010, 75-79.
13. Vetter F, Pohl J, Pohl B, Bracher F. Analysis of Cefaclor in novel chocolate-based camouflage capsule, *International Journal of Pharmaceutical Sciences,* 69(6), 2014, 455-457.
14. Attia K A M, Elabasawy N M, Abolmagd E. Simultaneous equation and area under the curve spectrophotometric methods for estimation of Cefaclor in presence of its acid induced degradation product; A comparative study, *Future Journal of Pharmaceutical Sciences,* 3(2), 2017, 1-5.
15. Ivama V M, Rodrigues L N C, Gauratini C C I, Zanoni M V B. Spectrophotometric determination of Cefaclor in pharmaceutical preparations, *Quim. Nova,* 22(2), 1999, 201-204.
16. Mishra K, Saragi B, Burala K K. Simultaneous estimation of sertraline and alprazolam in its bulk and tablet dosage form by RP-HPLC method, *Asian Pacific Journal of Pharmacy and Phytochemistry,* 1(1), 2016, 25-32.

17. Mishra K, Prasanna K D, Behera S R. Simultaneous estimation of sacubitril and valsartan in bulk and pharmaceutical dosage form by using RPHPLC, *Research Journal of Pharmacy and Life Sciences,* 1(2), 2020, 25-32.
18. Balamurugan K, Mishra K, Suresh R. Simultaneous estimation of linagliptin and metformin HCL in human plasma by RP-HPLC method, *International Research Journal of Pharmacy,* 10(1), 2019, 01-04.
19. Mishra K, Behera S R, Mishra S R, Somesu M, Kumar B K. A validated stability indicating RP-HPLC method development for platelet aggregation inhibitor ticagrelor in bulk and tablet formulation, *Journal of Global Pharma Technology,* 11(12), 2019, 12-18.
20. Mishra K, Kumar B K, Kumari M M, Subrahmanyam B S S. New analytical method development and validation of chlorpheniramine maleate by using UV-visible spectrophotometry, *Indo American Journal of Pharmaceutical Sciences,* 3(7), 2016, 767-772.
21. Mishra K, Behera S R, Sankar C G, Martha S K. Development and validation of stability indicating assay method (SIAM) for rabeprazole in rabeprazole sodium delayed release tablets using HPLC, *Research Journal of Pharmacy and Life Sciences,* 1(3), 2020, 89-97.
22. Sun L, Zhang W, Liu X, Sun J. Preparation and evaluation of sustained-release azithromycin tablets *in vitro* and *in vivo*, *Asian Journal of Pharmaceutical Sciences,* 9(3), 2014, 155-161.

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