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Novel Analytical Method Development and Validation for Cefotetan New β-Lactam Antibiotics in Bulk and Dosage Form

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ABSTRACT

The aspire and intention of the present study is to expand moreover authenticate a novel as well as rapid reverse phase chromatography separation technique for the estimating Cefotetan in bulk as such active pharmaceutical ingredient and dosage form to justify the presence of drug in the developed dosage forms and give satisfaction towards presence of medicine and its assay estimation. As the drug Cefotetan compendial monograph is not available in Indian Pharmacopoeia and British Pharmacopoeia, but a compendial monograph is available in United Sate Pharmacopoeia i.e. USP-40. USP monograph has a drawback that the standard solution and sample solution must be kept away from the light and to be used within 90 minutes after freshly preparation and which is time consuming, expensive and non eco-friendly method. To overcome these problems a new method is developed and validated in this research.

Keywords: chromatography, Cefotetan, HPLC method

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INTRODUCTION:

Cefotetan is a semi synthetic cephamycin antibiotics basically used to treat various bacterial infections [1]. Cefotetan administered intravenously or intramuscularly, it is highly resistant to a broad spectrum of β- lactamase and show efficacy towards wide range of both aerobic and anaerobic gram-positive and gram-negative microorganisms [1, 10].

Molecular formula of Cefotetan is $C_{17}H_{15}N_7Na_2O_8S_4$ and chemically Cefotetan is (6R,7S)-7-{4-[carbamoyl(carboxy) methylidene]-1,3-dithietane-2-amido}-7-methoxy-3-{[(1-methyl-1H-1,2,3,4-tetrazol-5-yl)sulfanyl]methyl}-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid[1, 3].

Molecular weight of Cefotetan is 575.623 g/mol, it is soluble in methanol, extremely soluble in water with pKa value 6.2 [5].

Literature survey indicated that very few analytical methods have been establishes for the qualitative and quantitative analysis of Cefotetan in bulk and dosage form [6,8]. However drug is widely used in pharmaceutical field for the treatment of bacterial infections and drug does not any Pharmacopoeial or compendial analytical method in IP and BP [2,3]. A monograph of drug is present in USP-40 which has a drawback that stock and sample solution prepared for analysis must be kept away from the light and to be used within 90 minutes after freshly preparation which make this method time consuming, not accurate in manner of adequate analysis, expensive and non eco friendly[4].

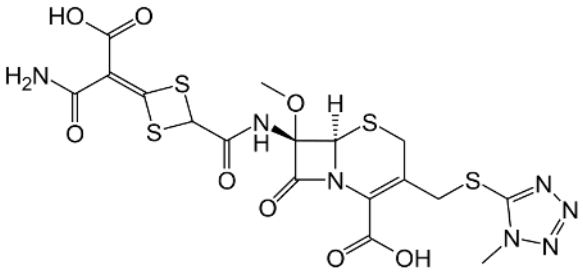

Fig.1: Chemical Structure of Cefotetan.

The objective of this work is to develop a new, simple, economic, rapid, eco friendly, accurate, and precise HPLC method for qualitative and quantitative estimation of Cefotetan in bulk and dosage form.