World Academy of Science, Engineering and Technology
International Journal of Pharmacological and Pharmaceutical Sciences
Vol:10, No:01, 2016

Development and Validation of a Rapid Turbidimetric Assay to Determine the Potency of Cefepime Hydrochloride in Powder Injectable Solution

Authors : Danilo F. Rodrigues, Hérida Regina N. Salgado

Abstract : Introduction: The emergence of resistant microorganisms to a large number of clinically approved antimicrobials has been increasing, which restrict the options for the treatment of bacterial infections. As a strategy, drugs with high antimicrobial activities are in evidence. Stands out a class of antimicrobial, the cephalosporins, having as fourth generation cefepime (CEF) a semi-synthetic product which has activity against various Gram-positive bacteria (e.g. oxacillin resistant Staphylococcus aureus) and Gram-negative (e.g. Pseudomonas aeruginosa) aerobic. There are few studies in the literature regarding the development of microbiological methodologies for the analysis of this antimicrobial, so researches in this area are highly relevant to optimize the analysis of this drug in the industry and ensure the quality of the marketed product. The development of microbiological methods for the analysis of antimicrobials has gained strength in recent years and has been highlighted in relation to physicochemical methods, especially because they make possible to determine the bioactivity of the drug against a microorganism. In this context, the aim of this work was the development and validation of a microbiological method for quantitative analysis of CEF in powder lyophilized for injectable solution by turbidimetric assay. Method: For performing the method, Staphylococcus aureus ATCC 6538 IAL 2082 was used as the test microorganism and the culture medium chosen was the Casoy broth. The test was performed using temperature control (35.0 °C ± 2.0 °C) and incubated for 4 hours in shaker. The readings of the results were made at a wavelength of 530 nm through a spectrophotometer. The turbidimetric microbiological method was validated by determining the following parameters: linearity, precision (repeatability and intermediate precision), accuracy and robustness, according to ICH guidelines. Results and discussion: Among the parameters evaluated for method validation, the linearity showed results suitable for both statistical analyses as the correlation coefficients (r) that went 0.9990 for CEF reference standard and 0.9997 for CEF sample. The precision presented the following values 1.86% (intraday), 0.84% (interday) and 0.71% (between analyst). The accuracy of the method has been proven through the recovery test where the mean value obtained was 99.92%. The robustness was verified by the parameters changing volume of culture medium, brand of culture medium, incubation time in shaker and wavelength. The potency of CEF present in the samples of lyophilized powder for injectable solution was 102.46%. Conclusion: The turbidimetric microbiological method proposed for quantification of CEF in lyophilized powder for solution for injectable showed being fast, linear, precise, accurate and robust, being in accordance with all the requirements, which can be used in routine analysis of quality control in the pharmaceutical industry as an option for microbiological analysis.

Keywords : cefepime hydrochloride, quality control, turbidimetric assay, validation
Conference Title : ICPSP 2016 : International Conference on Pharmaceutical Sciences and Pharmacology
Conference Location : Paris, France
Conference Dates : January 21-22, 2016