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Development and Validation of a Green Analytical Method for the Analysis of Daptomycin Injectable by Fourier-Transform Infrared Spectroscopy (FTIR)

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Abstract : Daptomycin is an important antimicrobial agent used in clinical practice nowadays, since it is very active against some Gram-positive bacteria that are particularly challenges for the medicine, such as methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococci (VRE). The importance of environmental preservation has receiving special attention since last years. Considering the evident need to protect the natural environment and the introduction of strict quality requirements regarding analytical procedures used in pharmaceutical analysis, the industries must seek environmentally friendly alternatives in relation to the analytical methods and other processes that they follow in their routine. In view of these factors, green analytical chemistry is prevalent and encouraged nowadays. In this context, infrared spectroscopy stands out. This is a method that does not use organic solvents and, although it is formally accepted for the identification of individual compounds, also allows the quantitation of substances. Considering that there are few green analytical methods described in literature for the analysis of daptomycin, the aim of this work was the development and validation of a green analytical method for the quantification of this drug in lyophilized powder for injectable solution, by Fourier-transform infrared spectroscopy (FT-IR). Method: Translucent potassium bromide pellets containing predetermined amounts of the drug were prepared and subjected to spectrophotometric analysis in the mid-infrared region. After obtaining the infrared spectrum and with the assistance of the IR Solution software, quantitative analysis was carried out in the spectral region between 1575 and 1700 cm-1, related to a carbonyl band of the daptomycin molecule, and this band had its height analyzed in terms of absorbance. The method was validated according to ICH guidelines regarding linearity, precision (repeatability and intermediate precision), accuracy and robustness. Results and discussion: The method showed to be linear ($r = 0.9999$), precise (RSD% < 2.0), accurate and robust, over a concentration range from 0.2 to 0.6 mg/pellet. In addition, this technique does not use organic solvents, which is one great advantage over the most common analytical methods. This fact contributes to minimize the generation of organic solvent waste by the industry and thereby reduces the impact of its activities on the environment. Conclusion: The validated method proved to be adequate to quantify daptomycin in lyophilized powder for injectable solution and can be used for its routine analysis in quality control. In addition, the proposed method is environmentally friendly, which is in line with the global trend.

Keywords : daptomycin, Fourier-transform infrared spectroscopy, green analytical chemistry, quality control, spectrometry in IR region
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