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Validation of Microbiological Assay for Determination of Cefuroxime in Injectable Preparations

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SUMMARY. The validation of a microbiological assay, applying agar diffusion method for determination of the active of cefuroxime in power for injection, is described. Using a strain of Micrococcus luteus ATCC 9341 as the test organism, cefuroxime was measured in concentrations ranging from 30.0 to 120.0 μ g/mL. The method validation showed that it is linear (r = 0.9999), precise (relative standard deviation = 0.37 %) and accurate (it measured the added quantities). Microbiological assay is satisfactory for quantitation of cefuroxime in powder for injection and the validity of the proposed bioassay, which is a simple and a useful alternative methodology for cefuroxime determination in routine quality control.

KEY WORDS: Cefuroxime, Cephalosporins, Microbiological assay, Quality control, Validation.

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