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# Development and Validation of a Turbidimetric Bioassay to Determine the Potency of Ertapenem Sodium

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**Abstract :** The microbiological turbidimetric assay allows the determination of potency of the drug, by measuring the turbidity (absorbance), caused by inhibition of microorganisms by ertapenem sodium. Ertapenem sodium (ERTM), a synthetic antimicrobial agent of the class of carbapenems, shows action against Gram-negative, Gram-positive, aerobic and anaerobic microorganisms. Turbidimetric assays are described in the literature for some antibiotics, but this method is not described for ertapenem. The objective of the present study was to develop and validate a simple, sensitive, precise and accurate microbiological assay by turbidimetry to quantify ertapenem sodium injectable as an alternative to the physicochemical methods described in the literature. Several preliminary tests were performed to choose the following parameters: Staphylococcus aureus ATCC 25923, IAL 1851, 8 % of inoculum, BHI culture medium, and aqueous solution of ertapenem sodium. 10.0 mL of sterile BHI culture medium were distributed in 20 tubes. 0.2 mL of solutions (standard and test), were added in tube, respectively S1, S2 and S3, and T1, T2 and T3, 0.8 mL of culture medium inoculated were transferred to each tube, according parallel lines 3 x 3 test. The tubes were incubated in shaker Marconi MA 420 at a temperature of 35.0 °C ± 2.0 °C for 4 hours. After this period, the growth of microorganisms was inhibited by addition of 0.5 mL of 12% formaldehyde solution in each tube. The absorbance was determined in Quimis Q-798DRM spectrophotometer at a wavelength of 530 nm. An analytical curve was constructed to obtain the equation of the line by the least-squares method and the linearity and parallelism was detected by ANOVA. The specificity of the method was proven by comparing the response obtained for the standard and the finished product. The precision was checked by testing the determination of ertapenem sodium in three days. The accuracy was determined by recovery test. The robustness was determined by comparing the results obtained by varying wavelength, brand of culture medium and volume of culture medium in the tubes. Statistical analysis showed that there is no deviation from linearity in the analytical curves of standard and test samples. The correlation coefficients were 0.9996 and 0.9998 for the standard and test samples, respectively. The specificity was confirmed by comparing the absorbance of the reference substance and test samples. The values obtained for intraday, interday and between analyst precision were 1.25%; 0.26%, 0.15% respectively. The amount of ertapenem sodium present in the samples analyzed, 99.87%, is consistent. The accuracy was proven by the recovery test, with value of 98.20%. The parameters varied did not affect the analysis of ertapenem sodium, confirming the robustness of this method. The turbidimetric assay is more versatile, faster and easier to apply than agar diffusion assay. The method is simple, rapid and accurate and can be used in routine analysis of quality control of formulations containing ertapenem sodium.

**Keywords :** ertapenem sodium, turbidimetric assay, quality control, validation
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