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ProtoCOL3 を用いた抗生物質の微生物学的力価試験法における阻止円の直径の測定に関する検討

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Assessment of Inhibitory Zone Diameter Measurement by ProtoCOL3 for Microbiological Assay of Antibiotics

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Summary

Microbiological assay is a bioassay that determines the potency of an antibiotic based on its antimicrobial activity, which is quantified by measuring the inhibitory zone diameter. The Zone Analyzer Systems ZA-FII (ZA; System Science, Co., Tokyo, Japan) is an automated zone diameter measurement device widely used in Japan. However, ZA production has been discontinued, so it is necessary to evaluate the suitability of a substitute device, ProtoCOL3 (Proto; Synoptics Ltd., Cambridge, England). Seven antibiotics (vancomycin hydrochloride, polymixin B sulfate, gentamicin sulfate, fosfomycin phenethylammonium, nystatin, erythromycin, and fradiomycin sulfate) were subjected to bioassay using the cylinder-plates method as outlined in the Japanese Pharmacopoeia 17th edition (JP). ZA measures the diameter directly (as defined in JP), whereas Proto calculates the diameter from measurements of the inhibitory zone area. The zone diameters on the plates were measured using both devices for comparative analysis. The variances in diameters measured using Proto and ZA were almost equivalent. However the reported diameters were larger with Proto than with ZA for all but one antibiotic (nystatin). In addition, the differences in diameters measured using Proto and ZA tended to be larger for the inhibitory zone diameters of "standard solutions of high concentration' than for 'sample solutions of high concentration." Consequently, the potency ratio of Proto to ZA was 0.974–1.006, and the potency calculated using Proto was lower than that using ZA for all antibiotics except nystatin. The observed differences may be caused by the different calibration methods and plate positions (fixed for Proto and rotated for ZA) during measurements. For the seven antibiotic bioassays, the average potency ratio of the two devices was 0.989, which is an acceptable margin. In conclusion, the Proto zone diameter measuring instrument can be used as a substitute device for ZA

Key words

Antibiotics, Microbiological assay, Japanese Pharmacopoeia, Inhibitory zone, Diameter, Zone Analyzer