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注射剤の不溶性異物検査法に関する研究
—検査条件の目視検査検知率への影響—

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Study on Foreign Insoluble Matter Test for Injections
—Effects of Inspection Conditions on Detection Rate—

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Summary

Light intensity, inspection environment and inspection time are the main factors that significantly influence the results of visual inspection of foreign insoluble matter in injections. In this study, we performed visual inspection of simulated samples containing foreign insoluble matter of various sizes, using different combinations of these three factors, and examined how they affected the inspection results. The results showed that higher average detection rates were obtained in visual inspection at 2,000, 3,000, 3,750 and 5,000 lx, as compared with 1,000 lx, which is extensively used in Japan. When inspecting glass ampoule and syringe samples containing various kinds of foreign matter at 3,000 lx, a change of inspection time in the range of 5 to 15 sec had little effect on the detection rate. The detection rate was not affected by the use of a white or black background, with or without a side shield. Based on these results, we discuss the optimum inspection conditions for "Foreign Insoluble Matter Test for Injections" as a quality test.

Key words

Foreign insoluble matter test, Detection rate, Light intensity, Inspection time, Inspection environment