

医薬品等汚染原因として報告された細菌の無菌試験法用培地での検出の検証*³

林 克彦*^{1, #}, 上原 由依加*², 森田 雄二*², 大屋 賢司*¹, 工藤 由起子*¹

(受付：令和6年3月28日，受理：令和6年11月27日)

Verification of Detection of Bacteria Present as Contaminants in Pharmaceuticals Using the Media for the Japanese Pharmacopoeia Sterility Test*³

Katsuhiko HAYASHI*^{1, #}, Yuika UEHARA*², Yuji MORITA*², Kenji OHYA*¹ and Yukiko HARA-KUDO*¹

Summary

Sterile pharmaceutical products are required to be free from microbial contamination as determined using the Sterility Test in the Japanese Pharmacopoeia. In this test, the products are cultured in fluid thioglycollate medium (FTM) and soya-bean casein digest medium (SCDM) for at least 14 days to detect microbial growth. Previously, we examined the suitability of FTM and SCDM to detect five micro-organism species (*Bacillus subtilis*, *Candida albicans*, *Clostridium sporogenes*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*) described in the Sterility Test and three bacterial species (*Methylobacterium extorquens*, *Mycobacterium chelonae*, and *Serratia marcescens* subsp. *marcescens*) that have been identified in recalled pharmaceuticals. However, not all micro-organisms inoculated at the level of 10 colony forming units (CFU) were detected in FTM and SCDM, and incubation for 28 days was necessary to detect *M. extorquens* in SCDM. Further, the detectability of other bacteria identified in recalled pharmaceuticals, such as *Burkholderia cepacia*, *Pseudomonas fluorescens*, *Ralstonia pickettii*, has not been verified yet. Therefore, this study aims to investigate the suitability of FTM and SCDM for detecting *B. cepacia*, *P. fluorescens*, *R. pickettii*, and *M. extorquens* inoculated at the levels of 10 and 100 CFU. After inoculation of 100 CFU, all bacteria were detected in both media, except for *M. extorquens* in FTM. After inoculation of 10 CFU, *B. cepacia*, *M. extorquens*, *P. fluorescens*, and *R. pickettii* were all detected in SCDM. However, *M. extorquens* in SCDM required at least 28 days for detection. Furthermore, although *B. cepacia* and *P. fluorescens* were detected in FTM, *R. pickettii* and *M. extorquens* were not completely detected at the 10 CFU level. These results suggest that different culture media or alternative detection methods are needed to ensure reliable detection of *M. extorquens*.

Key words

Japanese Pharmacopoeia, Sterility Test, Fluid thioglycollate medium, Soya-bean casein digest medium