

## 第十七改正日本薬局方<5.02>生薬及び生薬を主たる原料とする 製剤の微生物限度試験法における酵素基質培地の利用

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Study on the Use of Chromogenic Media in the 17th Edition of the Japanese  
Pharmacopoeia <5.02> Microbial Limit Test for Crude Drugs and Preparations  
Containing Crude Drugs as Main Ingredient

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### Summary

In association with the revision of the Japanese Pharmacopoeia from the 16th Edition to the 17th Edition, <5.02>Microbial Limit Test for Crude Drugs was changed to <5.02>Microbial Limit Test for Crude Drugs and Preparations containing Crude Drugs as Main Ingredient, which was established based on <4.05>Microbial Limit Test taking account of the special properties of crude drugs (such as high bioburden). In this revision, chromogenic media are allowed to be used in tests for *E. coli* and *Salmonella* as an alternative to conventional MacConkey Agar Medium and XLD Agar Medium. In order to validate this change, we performed growth promotion and recovery tests using various chromogenic media.

The tests have confirmed that representative commercially available chromogenic media (13 products for *E. coli* and 8 products for *Salmonella*) conform to the requirements of the growth promotion test specified under the revised test method. Recovery tests were performed with samples of *Glycyrrhiza* and *Ginseng* inoculated with *E. coli* and *Salmonella*. As a result, the inoculated micro-organisms were recovered in the test for *E. coli* in *Ginseng* and in the test for *Salmonella* in *Glycyrrhiza* and *Ginseng*. In the test for *E. coli* in *Glycyrrhiza*, however, the inoculated *E. coli* were indistinguishable in many media due to the growth of sample-derived bacteria, but at least the test demonstrated that *E. coli* were detectable even in presence of contaminating bacteria. The above results have demonstrated that chromogenic media can be used in the tests for *E. coli* and *Salmonella* in crude drugs.

### Key words

Microbiological limit test, Preparations containing crude drugs, Specified microorganism tests, Crude drug, Conventional crude drug product, Chromogenic medium