

漢方製剤, 生薬製剤及び生薬の残留農薬について (第1報)

漢方製剤及び生薬製剤の残留農薬に関する
日漢協自主基準並びに漢方製剤に関する実態調査

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**Pesticide Residues in Kampo Formulations, Crude Drug
Formulations and Crude Drugs (1)**

**Self-Imposed Limits of Pesticides Residues and
Survey of Their Implementation in Kampo Formulations**

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Summary

In 1996, Japan Kampo Medicine Manufacturers Association (JKMA) set up self-imposed limits of residual pesticides for Kampo formulations and crude drug formulations containing ginseng and/or senna leaf (organochlorine insecticides). Recently, however, pesticide residues have been detected in crude drugs imported mainly from China. Therefore, JKMA revised the self-imposed test method and limits of pesticide residues for Kampo formulations, crude drug formulations and crude drugs in June 2005. The first point of the revision is the expansion of the self-imposed limits on organochlorine insecticides to 11 kinds of crude drugs (Table 2) and to Kampo and crude drug formulations containing the 11 crude drugs. Secondly, we set up residual limits of organophosphorus and pyrethroid insecticides in Kampo formulations containing specific crude drugs (Table 2).

The first section of this report deals with the recoveries of added pesticides and the detection limits of the recommended test method, and these results are shown in Tables 4, 6 and 7. Then, we introduce our survey results on the actual implementation of the self-regulation for Kampo formulations. Among 75 member companies, 57% have implemented pesticide tests 9 months after starting the revised self-regulation. The test results of more than 2,832 samples are summarized in Table 8. None of the samples contains the pesticide residues at levels higher than the recommended residual limits for Kampo formulations.

Key words

Pesticide residue, Kampo Formulation, Crude drug formulation, Crude drug, Astragalus Root, Polygala Root, Glycyrrhiza, Cinnamon Bark, Asiasarum Root, Cornus Fruit, Perilla Herb, Jujube, Citrus Unshiu Peel, Loquat Leaf, Moutan Bark