

# **The current situation of the assay of herbal medicines**

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Growing evidence has suggested the usefulness of herbal medicines to treat various diseases. In Japan, similar to Chinese herbal medicines, traditional medicines, including herbal products named “Kanpo,” have been used for over a thousand year and are currently being used in combination with the modern drug therapy.

In general, TDM would be needed if drug with the narrow therapeutic range shows their serious outcomes, including ADRs, when administered outside the therapeutic range. All herbal medicines, including “Kanpo,” contain several herbs and other materials. However, the important (i.e., pharmacologically-effective) compounds among these various ingredients are mostly not well known. Moreover, the information about the blood levels of such important compounds and their therapeutic range is unavailable in many cases. Thus, to date, there are not so any meant during the use of herbal medicines to assay a single compound to adjust the dosage by TDM. Indeed, national health insurance in Japan does not cover TDM to measure any “Kanpo”/herbal medicine-related compounds.

However, rational development of analytical technique enables rapid identification of such important compounds from herbal medicines. Moreover, blood levels of such compounds in most *in vivo* animal experiments can be measured using sensitive machines such as UPLC-MS/MS although there are still many technical difficulties. In this presentation, I will illustrate recent examples and underlying problems associated with the assay of herbal medicines.