Editorial

Key Issues for Quality Control of Natural Medicinal Products

Traditional medicines have been utilized worldwide. Key issues on using the medicines in a modern medical care system are described below.

In general, a medicinal product consists of an active principle (active pharmaceutical ingredient: API) and additives, and quality evaluation is made for them. An API plays a central role in a medicinal product. It is evaluated from various points of view such as description, identification (e.g. UV, IR and qualitative tests), pH, melting point, purity (e.g. clarity and color of solution, heavy metals, fingerprinting for related substances), loss of drying, residue of ignition, and assay in a Western medicine. On the other hand, all of such test items cannot be adopted for traditional medicines because of special circumstances in natural products. Under these circumstances, there are two premises in using traditional medicines in a modern medical care system; i.e. (1) equivalency between modernized traditional medicines (e.g. extract products) and ancient ones (e.g. decoction), and (2) quality evaluated by modern science.

(1) Modernized traditional medicines shall be assured equivalent to ancient ones. Historical facts of manufacturing processes from an era to another, adoption of manufacturing processes in classical texts, and confirmation of equivalency between modernized traditional medicines and ancient ones can link the past with the present and can assure efficacy and safety of modernized traditional medicines. In Japan, extract products, whose quality is equivalent to standard decoctions, have been marketed as Kampo extract products.

(2) Contaminants such as heavy metals, residual pesticides, and/or microorganism, and intentional adulteration of active ingredients cause a number of human sufferings. Safety of traditional medicines depends on quality of the products. Quality evaluation methods used for Western medicines cannot directly be applied to modernized traditional medicines; thus, manufacturing controls as well as quality controls are absolutely required to obtain high-quality products.

In case of an extract product, what can be considered as an API? Is it a chemical compound, a natural raw material, or extract? Extract is the answer in the case. Chemical compounds are ingredients of natural raw materials; natural raw materials are components of traditional formulas; and extract is an API of an extract product. Quality of medicinal products depends on that of APIs and it is very important to control manufacturing and quality of APIs; however, situations in natural medicines are complicated as shown below.

Case A: Mixture of extracts individually obtained from raw botanical/animal/mineral materials

In this case, a finished product is considered a combination product, and "**each extract**" derived from a raw botanical/animal/mineral material is an API. Quality assurance of each extract is important. An overall pattern of each extract should be strictly controlled.

Case B: Extract obtained from mixture of raw botanical/animal/mineral materials

In this case, a finished product can also be considered a combination product; however, "**whole extract**" derived from raw botanical/animal/mineral materials is an API. An overall pattern of whole extract should be strictly controlled.

It is known that constituent profiles of extracts can be different between the above cases if natural materials contain alkaloids. This is important in considering APIs. For these years, international standardization of traditional medicines in East Asia including TCM, Kampo medicines and Korean medicines has been facilitated; however, we have more than one way of thinking on APIs. Difference in manufacturing processes requires different control items. We should bear in mind different targets in quality assurance of traditional medicines.

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