

Foreword

The Past, Present and Future of Kampo Extract Preparations in Japan

Kampo extract preparations typically known throughout the world today are produced by crude herbs—originally for traditional formulations of decoction, pill and powder—decocting in water, extracting their active ingredients, then adding an excipient. This technology was developed in Japan.

Kampo extract preparations have been developed and subject to clinical tests by Dr. Takeshi Itakura from as early as the first half of the 1940s. Dr. Itakura's research was thereafter suspended, but in 1950, Dr. Takeshi Watanabe completed the original form of today's extract preparations, and in the mid-1950s, a number of pharmaceutical companies commercialized them and began selling them in pharmacies. Extract preparations were first widely available over-the-counter (OTC) before they were approved as ethical drugs in 1976.

This development allowed physicians to handle Kampo medicine in a convenient manner—in prescription units—at medical facilities covered by health insurance which Kampo medicine were previously irrelevant. Extract preparations were originally recognized as an alternative to decoctions, but their market steadily expanded thereafter owing to their convenience, such that they have come to be used widely in the medical field in place of decoctions.

There are 148 types of extract preparations in Japan. One of their salient characteristics is that they are each made according to a fixed formula prescription. Extract preparations are rigidly regulated by the Ministry of Health, Labour and Welfare, from their raw ingredients to production process. They ensure high quality as meeting an advanced Kampo GMP that pharmaceutical manufacturers voluntarily establish in addition to general GMP. Owing to this, it has become possible to conduct diverse clinical trials, and in fact, a number of case series and RCT have emerged today, and are expected to increase even more hereafter.

The second characteristic is that approximately half of all prescriptions are sourced on the *Shokanron* (*Shan Hang Lun*) and *Kinkyoryaku* (*Jin Gui Yao Lue*). These classic preparations, from which Kampo medicine was derived, started being used frequently in Japan from around 300 years ago, and have provided a rich accumulation of experience to practitioners. Their extremely sophisticated content, high clinical value, and wide scope of applications have greatly contributed to popularizing extract preparations in Japan.

The indications of Kampo extract preparations were widely studied along with the development of modern medicine, and they came to be used for the treatment of a diversity of diseases beyond comparison with those in ancient China. The study of their side effects has also advanced, and sufficient knowledge of their safety has spread. Although the market is extremely small, worth merely around 140 billion yen, Kampo extract preparations play an extremely large role in supporting Japanese medical and healthcare field. Their needs will undoubtedly continue to grow in the future.

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