

Innovation of Consistency

Consistency Across the Entire Kampo Value Chain

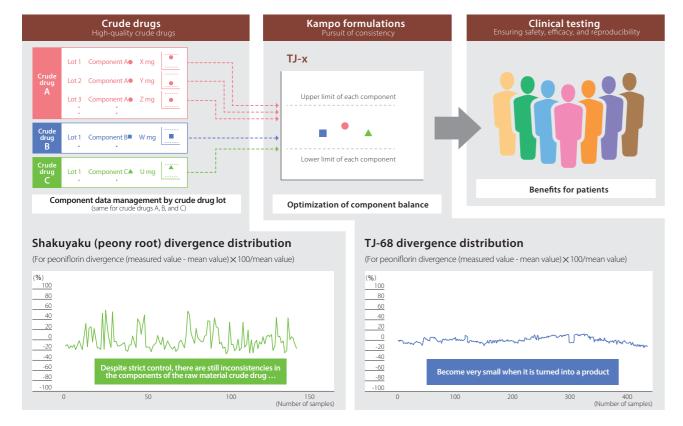
Since crude drugs are natural substances, the component content varies depending on factors such as production area, cultivation environment, and processing and storage conditions. However, they must achieve clinical reproducibility in order to become pharmaceutical products, and this is ensured by stable quality of crude drugs and the technology and expertise to create consistent Kampo products in the formulation process.

Such consistency has been considered difficult to achieve in the finished Kampo formulation products, because even if they are grown from seeds or seedlings from the same origin, crude drugs may vary in their shape or component content due to factors including growing environment, such as soil or climate, harvest timing, and storage conditions. The Tsumura Group has built the Kampo value chain, a proprietary supply chain that manages business activities consistently from upstream to downstream. To achieve consistency, it is vital to pursue quality throughout the entire Kampo value chain. In the upstream process of crude drug cultivation, we

control variation in raw material crude drugs by providing guidance on cultivation and processing methods and using only crude drugs that meet Tsumura's quality standards. The component balance of the crude drugs can be further optimized in the formulation process by analyzing and managing the component content data for each lot, then prescribing the ratio of the crude drug lots to be used in the preparation. In the formulation process, to minimize changes to the components of the extract, we have developed a proprietary manufacturing line and we control the system for each formulation to achieve consistency in our final Kampo formulation products.

These activities are truly the practical embodiment of our Corporate Value, "The Best of Nature and Science," and we will continue to hone our strengths in safety, efficacy, and consistency, aiming to contribute to the solution of social issues through business, such as protection of human health, preservation of the global environment, and revitalization of local communities.

Consistency and Clinical Reproducibility of Kampo Medicines





Future Development

Development of Business in China Leveraging the Tsumura Group's Strengths

In Japan, the portion of the population aged 65 and over surpassed that aged under 14 in 1997, and the country is now known as the fastest aging country in the world. However, population aging is advancing globally, and the portion of the population aged 65 and over (aging ratio) is expected to increase rapidly over the next 40 years.

China is also experiencing a falling birthrate and aging population. The Tsumura Group has defined its vision for the China business as contributing to the health of the citizens of China through its accumulated technology and experience, and is steadily putting it into action.

The Healthy China 2030 initiative promoted by the Chinese government places importance on both modern medicine and Chinese medicine. It promotes the development of rules regarding traditional Chinese medicine production and also encourages expanding the scale of production. Within traditional Chinese medicines also, the key to the development of traditional Chinese medicinal products is

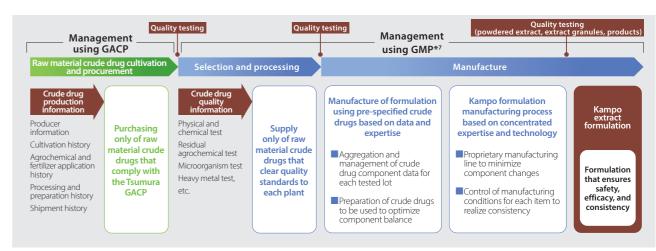
standardization, and the Chinese government views the standardization of traditional Chinese medicinal products as a priority issue. The Tsumura Group seeks to achieve the standardization of traditional Chinese medicinal products and contribute to the development of the Chinese medicine industry. We will do this by using our technologies and expertise related to safety, efficacy, and consistency, which have been honed in the Kampo business.

In addition, with regard to the sale of raw material crude drugs and drug pieces, we will contribute to the citizens of China and healthcare by supplying high-value-added services using high-quality crude drugs.

We aim to continue striving to be a corporate group that contributes to the well-being of people, societies, and the environment globally by working to create shared value with all stakeholders involved in our value chain, and to popularize pharmaceutical products derived from natural substances.

⇒For details, see page 53 "Strategic Challenge 3".

Process for Managing Consistency



^{*7} Good Manufacturing Practice. A Ministry of Health, Labour and Welfare ordinance that sets out permission requirements for the manufacturing of pharmaceutical products and quasi-pharmaceutical products, as well as requirements for obtaining marketing authorization, with manufacturing management and quality control standards for pharmaceutical products and quasi-pharmaceutical products.

TSUMURA Integrated Report 2023 34