

Feature:

“The Best of Nature and Science” – Tsumura’s Value Creation Capability

Guided by its Corporate Value, “The Best of Nature and Science,” the Tsumura Group has grown as a leading company in prescription Kampo formulations through its pursuit of safety, efficacy, and consistency in its pharmaceutical products, based on scientific evidence. Trust and a performance record built up on the medical front line, along with research driven by advanced technologies, are the sources of Tsumura’s competitive advantage, and its unique value creation capability.



Pursuit of Safety

Quality of Kampo Products Begins from the Growing Fields

The Tsumura Group insists on the safety of raw material crude drugs and applies rigorous quality management as a manufacturer of Kampo and traditional Chinese medicines using crude drugs from plants and minerals found in nature.

Around 90% of the Group’s raw material crude drugs are procured from China. However, we do not purchase crude drugs from crude-drug markets throughout China. This is because the crude drugs that circulate in the markets are incredibly challenging to trace with regard to where and by what methods they were cultivated and processed. Based on our policy that the quality of Kampo products begins from the growing fields, we spent many months establishing a system for directly purchasing crude drugs from production areas. Furthermore, we referred to Good Agricultural Practices to ensure management of agricultural production processes for constant improvement, and built our own Tsumura GACP with additional training, audit, and certification systems.

Under the Tsumura GACP, processes from planting to cultivation methods, use of agrochemicals and fertilizers, harvesting, and processing are all determined by Tsumura GACP Guidelines based on our proprietary quality management standard, the Tsumura GACP Guidelines. We enter contracts with production groups that have acquired the Tsumura GACP Certification and purchase raw material crude drugs from them. This leads to stable income for producers and sustainable agricultural management.

In addition, we have built a crude drug traceability system that enables us to trace information such as which fertilizers or agrochemicals are used, and the cultivation history. Not only does this make it possible to take upstream safety measures against foreign contaminants such as agrochemical residues or

microorganisms, but it also means that we can trace and check all processes up to delivery to the medical institutions by matching the history information for the Kampo formulation manufacturing process and logistics steps.

Raw material crude drugs procured through contract producers across China are concentrated mainly at SHENZHEN TSUMURA MEDICINE and CHINA MEDICO CORPORATION. The raw material crude drugs are tested for safety, such as agrochemical residues, microorganisms, and heavy metals, and undergo physical and chemical testing to remove any foreign objects and defective products. Only raw material crude drugs that clear quality standards are supplied to each plant, where they are manufactured into Kampo formulations.

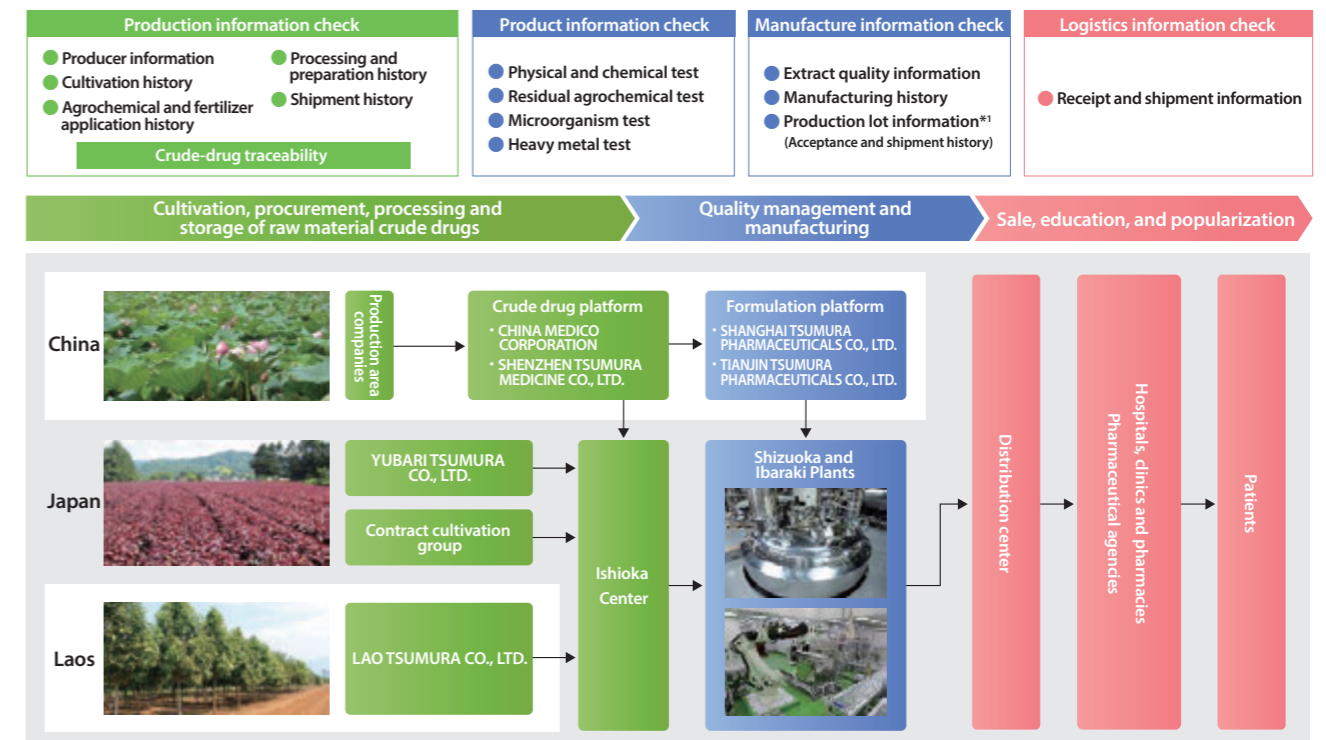
Moreover, the Group manages its own fields where it can provide cultivation instruction directly, and it is expanding the ratio of such fields. In this way, we are working to strengthen the raw material crude drug quality assurance system and stabilize prices.

In our quality testing, we conduct tests prescribed in the Japanese Pharmacopoeia, as well as testing for residual agrochemicals, microorganisms, mold toxins, and elemental impurities under our own in-house specifications and our own standards. We are also working to ensure safety by developing proprietary technologies for analyzing crude drugs and Kampo extract powder and granules that contain multiple and diverse components.

Crude drug varieties used in the Japan business

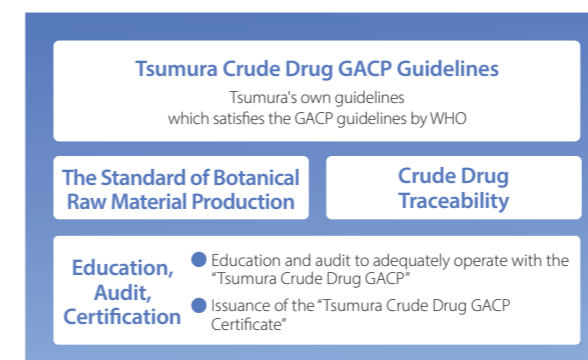
Plant-based 110 Animal-based 5 Mineral-based 4

Tsumura Traceability System



*1 Groups of products made under the same conditions are referred to as a lot. The smallest unit of information when producing products is referred to as production lot information.

Tsumura GACP Guidelines



PDCA Cycle in the GACP

