

Research and development

Strength 1 Ability to undertake research and analysis of original drug patents

By utilizing both human assets with extensive experience in patent trials and proceedings and a proprietary database that includes information on patents and proceedings in Japan and overseas, we implement an extremely sophisticated patent strategy. We develop the optimal patent strategy for new issues in collaboration with patent attorneys in Japan and overseas who possess broad knowledge of pharmaceuticals.

In recent years, we have also been keeping an eye on

intellectual property trends in the U.S. and Europe and leverage those trends for our intellectual property strategy for Japan. In particular, it is possible to learn a lot from applying for paragraph IV certification in the U.S., and this is a major asset that supports future business activities, which is one of our strengths.

Number of patents held
45
Sawai Pharmaceutical

Strength 2 Formulation technology capabilities based on human assets with expertise in API properties and formulation technology

Another of our Group's strengths is our formulation technology capabilities, one aspect of which is collecting the latest information related to APIs and formulation from throughout the world, and this makes it possible to conduct development in line with international harmonization. Furthermore, we have increased the certainty of our product launches by continually revising and bringing forward development plans. Even while busy with product development, we actively take on the challenge of research linked to future development topics and aggressively work

to accumulate and expand our formulation technology.

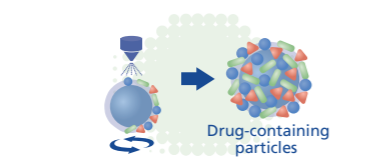
We will provide drugs that meet the needs of healthcare professionals and patients and introduce first-of-their-kind products using SAWAI HARMOTECH®, a series of formulation technologies born from this research.

R&D expenses
¥12.5 billion
Sawai Pharmaceutical

Number of R&D Division staff
295
Sawai Pharmaceutical

SAWAI HARMOTECH®
Sawai Pharmaceutical's main formulation technology

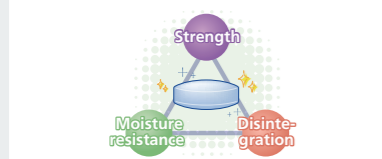
Core particle production technology **QALCORE®**



Drug-containing particles

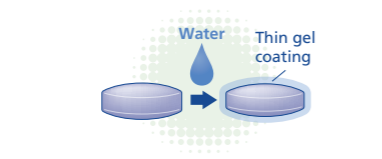
Dry coating, wet coating, and wet adsorption method are three core particle production technologies that allow us to reduce production time and make products comfortable for patients to take.

OD tablet production technology **SARAMEL®**




Our original additive SARAMEL is a patented technology of Sawai that makes it possible to produce tablets with outstanding strength, moisture resistance, and disintegration properties by simply mixing with API.

Film coating technology **THRUCOAT®**




With this technology, a gel coating forms on the surface by moisturizing with water, creating tablets that are easy to take with little force. This makes it easier to take the medicine.

Escitalopram OD Tablets
QALCORE® SARAMEL®



Dia. 7 mm

Levetiracetam Granular Tablets
THRUCOAT®



Dia. 2.1 mm

Message from responsible officer (R&D)

Taking on the challenge of new businesses in addition to being the first to introduce generic drugs

To undertake product development, which has grown more difficult in recent years, we are not only increasing research efficiency through DX but are also broadly strengthening our R&D foundation, which includes actively undertaking joint research with such entities as independent research institutes and researching physiological models that do not employ animal testing.

We will take on the challenge of being the first to introduce generic drugs and launching new businesses so that no suffering patients are left behind, and this entails developing drugs for rare diseases that lack sufficient treatments and similar activities.



Shoji Yokota, Ph.D.
Director,
Senior Managing
Executive Officer,
Group Chief
Research &
Development Officer

Message from responsible officer (IP)

Promoting robust intellectual property capabilities, including those for new business fields

Having handled patent cases, mainly those related to generic drugs, in the past, we will strive to strengthen our intellectual property capabilities in new fields, such as digital medical devices in the future.

Furthermore, we will work to maximize the value of intangible assets throughout the Group by strengthening measures related to training personnel who possess specialized knowledge in various fields, such as intellectual property, formulation, and property analysis; undertaking and maintaining systematic and comprehensive activities, including the formulation of an advanced intellectual property strategy; and promoting the protection and branding of intellectual property, Sawai's original technology, centered on SAWAI HARMOTECH®.



Nobuko Sugimoto
Senior Executive
Officer,
Group Chief
Intellectual
Property Officer

Procurement

Strength 1 Strong new product API research and procurement abilities

As for APIs used in new development, we undertake various activities such as searching for APIs throughout the world, examining production facilities, quality, etc., and conducting analysis and trial production of pharmaceuticals using samples of these APIs. We use APIs that meet our own standards, which are even higher than those of the Ministry of Health, Labour and Welfare. The API Sourcing Group provides support for research and procurement through its specialists in purchasing, including members with experience at new drug manufacturers, API trading companies, and Sawai factories.

Suppliers

Procure a wide range of raw materials from around **500 companies** in **30 countries** throughout the world

Strength 2 Selection and procurement of raw materials with primary emphasis on quality and safety

In order to deliver even higher quality generic drugs, we inspect the factories of API manufacturers, particularly the Quality Assurance Department. Furthermore, we confirm that API manufacturers' quality management systems meet Sawai standards by checking that the Production Department undertakes manufacturing in an appropriate environment and the Quality Control Department conducts appropriate analysis. We also release information on the country and factory where APIs are manufactured to provide healthcare professionals with peace of mind. In addition, we actively undertake multisourcing—that is, procuring the same API from multiple manufacturers in order to ensure stable procurement.

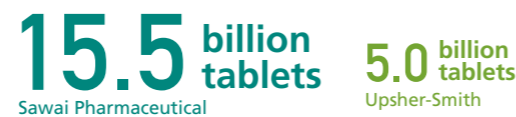
Production and reliability assurance

Strength 1 Manufacturing know-how for high-mix, low-volume production

To produce various types of generic drugs using the same machinery, it is vital to possess know-how regarding preventing the mixing of principal ingredients.

For tablet presses that form granules into tablets, it takes almost one whole day to switch between products, and Sawai ensures safety by validating each cleaning procedure. This know-how related to validating unique generic drug production processes and managing production makes it possible to conduct high-mix, low-volume production and ensure quality.

Production capacity



Number of products approved to manufacture



* Calculated according to the counting standards of Japan

Strength 2 Stringent quality management

Quality is managed to exceed government standards through all process, from selection of API and additives to production process, and even post-sales.

We are working to further improve our uncompromising quality in order to provide generic drugs that can be used with peace of mind.

Number of staff in Quality Control Department



Strength 3 Own production factories located throughout Japan and external partner companies

Production management and quality control are undertaken, primarily for our eight main factories in Japan. All eight factories observe GMP, and we strive to implement continual improvements by acting in concert and sharing the findings of audits.

We also conduct audits of formulation manufacturing subcontractors at least once every three years.

Number of internal GMP audits



Message from responsible officer

Embodying the Group philosophy through continuous efforts to improve quality

The Group has expanded its production capacity within Japan to 18.5 billion tablets, which includes 15.5 billion tablets for Sawai Pharmaceutical's six factories (Kashima, Kanto, Sanda, Sanda Nishi, Kyushu, Daini Kyushu), and 3.0 billion tablets for Trust Pharmatech's Yachi and Seima factories.

Through not only this production capacity but also continually implementing measures to increase quality, we aim to embody the Group's philosophy of "always putting healthier lives first."



Toshiya Hasuo
Senior Executive Officer
Group Chief
Production Officer

Topics Working to establish a production system at Trust Pharmatech

Founded as a new subsidiary of the Group in December 2021, Trust Pharmatech launched full production in April 2023 and is moving forward with efforts to establish a production system with an annual capacity of 2.0 billion tablets or more in 2024.

The most important efforts are thoroughly introducing and spreading the corporate philosophy of "always putting patients first" and Sawai quality just like has been done at Sawai Pharmaceutical. In order to spread the corporate philosophy to each and every employee and encourage its implementation, we systematically undertake training and group activities to raise compliance awareness. We are also rebuilding our GMP system and providing continual employee education to spread the Sawai culture regarding quality.

Furthermore, we are transferring production to factories in a planned manner. As for new products, in addition to passing on Sawai standards based on witnessed manufacturing and testing by the Research and Development Division, Sawai Pharmaceutical

employees provide onsite guidance for producing and testing existing products. Even for ensuring quality, Sawai Pharmaceutical offers support on all fronts, such as holding guidance meetings and conducting audits by the responsible person in the Quality Assurance Department and Reliability Assurance Division.

Our goal is to achieve an annual production capacity of 3.0 billion tablets in the future by increasing the number of employees involved in manufacturing through 2025.



Trust Pharmatech's Seima Factory 2

Sales and marketing

Strength 1 Provision of accurate information

We provide information to patients and healthcare professionals through three channels—approximately 370 medical representatives (MRs); the Medical Information Center, an inquiry desk open 24 hours a day, 365 days a year; and a website.

In addition to undertaking activities for providing accurate information to all healthcare professionals, MRs collect and compile information on side-effects and safety of drugs, and this work is led by the Pharmacovigilance Department. We are working to have our drugs properly used by providing that information to healthcare workplaces as feedback.

Number of MRs



Strength 2 Extensive product lineup

The lineup of products offered by our Japanese Group companies extends to about 800 products. Our ability not only to collect and provide information on various diseases and in a wide range of fields but also to broadly meet the treatment policies and needs of healthcare professionals, which is possible because we market numerous products, is another strength of Sawai Group.

On account of our continuing training for MRs that covers various products, MRs can acquire extensive knowledge. It is precisely because of our wide lineup of products, that we can propose multiple drugs to treat the same disease and more concomitant drugs.

Number of products on sale



* Calculated according to the counting standards of Japan