



Production and reliability assurance

Ensuring stable supply

In order to deliver a stable supply of high-quality generic drugs, which require high-mix, low-volume production, we have developed an industry-leading production system equipped with the latest facilities. As our generic drug sales have reached approximately 14.8 billion tablets, which accounts for approximately 8% of sales volume in Japan, we serve as an essential part of the Japanese healthcare infrastructure.



Stringent quality management

To ensure quality management, we have established standards that exceed national standards in all processes from the selection of APIs and additives to manufacturing processes and after sales. We make uncompromising efforts to improve quality with the aim of providing even better generic drugs that everyone can use with peace of mind.

Production capacity	Number of staff in Quality Management Department	Number of internal GMP audits
Approx. 15.5 billion tablets Sawai Pharmaceutical	393 Sawai Pharmaceutical	141 Sawai Pharmaceutical
Approx. 3.6 billion tablets Upsher-Smith	67 Upsher-Smith	69 Upsher-Smith

Sawai's strengths

- Stringent quality management
- Ability to offer a stable supply of drugs using our own production factories located throughout Japan and external partner companies
- Manufacturing know-how for high-mix, low-volume production

At our formulation factories, we implement manufacturing management and quality control in compliance with GMP

Furthermore, in accordance with GQP standards, Head Office and the Quality Assurance Department constantly check whether manufacturing factories observe GMP through onsite verifications, etc. to confirm that manufacturing management and quality control comply with standards. Because it was difficult to conduct onsite audits during the COVID-19 pandemic, we launched remote audits as a new measure and aggressively moved forward with onsite audits by third-party organizations.

In the supply chain, we also conduct audits of API manufacturers at least once every five years and formulation manufacturing subcontractors at least once every three years.

Active pharmaceutical ingredients (APIs) country of manufacture disclosure

Sawai Pharmaceutical

Since July 2019, we have made public the "API country of manufacture" and "final drug substance manufacturing locations," for our products on Sawai Pharmaceutical's comprehensive information website for healthcare professionals and continue to disclose the name of formulation manufacturing companies.

We disclose information on the percentage of API manufacturing countries and final drug substance manufacturing locations by country and the date onsite audits were conducted at final drug substance manufacturing locations and formulation manufacturing companies so that healthcare professionals can use drugs sold by the Company with peace of mind.

Aiming to establish an in-house production system for more than 20.0 billion tablets

It was decided to construct a new solid dosage form facility at the Daini Kyushu Factory as one of the measures to establish an in-house production system for more than 20.0 billion tablets, which was included in the Medium-Term Business Plan START 2024. This is being done to respond to various problems that the industry faces, such as ones related to quality and supply, and to further increase the Company's market share. Plans are broken into two steps.

In step 1, production capacity of 2.0 billion tablets will be added in 2024, and in step 2, production capacity of 1.0 billion tablets will be added while we keep an eye on market trends and new product development.



Daini Kyushu Factory
Image of New Solid Dosage Form Facility

Message from the Group CQO

Working to establish a firm Sawai brand

Distrust of generic drugs (GE drugs) has grown because of problems related to quality and supply that have their roots in scandals at GE drug manufacturers. Last year, Sawai Pharmaceutical, the core of the Sawai Group, implemented various efforts to rebuild that trust. The management team issued a declaration both in-house and outside the Company that it would comply with laws and regulations and once again clearly indicated the role of each responsible party within the drug production and sales business. Furthermore, we worked to lead the industry by conducting voluntary inspections of approval forms, disclosing not only the name of formulation manufacturing companies but also the date of GMP local audits at API and formulation factories, and actively responding to the various laws and regulation. We will also listen to the opinion of all stakeholders and actively work on various fronts, including promptly sharing information.

This year, we newly added Trust Pharmatech Co., Ltd. to the Group. Under a uniform quality and safety policy for



Toru Terashima

Director,
Senior Executive Officer,
and Group Chief Quality & Safety Officer

the whole Group, we will strictly manage the quality and safety of the overall business, including new businesses. Society is keeping a wary eye on quality fraud by companies, and proper quality management is an important management issue. Under the motto "always putting healthier lives first," the Sawai Group wants to become a corporate group that continues to contribute to society and is always steadily improving.

Topics

Establishing Trust Pharmatech —the start of a new challenge to regain trust

On April 1, 2022, we officially launched a new business. Employees from Kobayashi Kako, Co., Ltd. which account for more than 90% of employees, not only reviewed operation details and completed supplementary operations but also energetically undertook various other activities, including retaking courses on compliance, GMP, and other topics, while also implementing various improvements and revising procedures. Since the announcement of the December 2021 transfer of assets related to production activities and employees to the Sawai Group, employees relearned compliance, the Pharmaceuticals and Medical Devices Act, and GMP; spent extensive time gaining an understanding of the various GMP procedures; set and announced action targets for each worksite at the end



Touring local facilities



Transferred employees receiving training

Toshiya Hasuo
President
Trust Pharmatech Co., Ltd.



of April; and launched work to build trust throughout the Company.

In order to use our production facilities, which can produce 3.0 billion tablets annually, and offer a stable supply as quickly as possible, numerous employees were dispatched to Sawai Pharmaceutical to receive training. Furthermore, technicians from Sawai Pharmaceutical were invited to work on in-house production preparations, and efforts to achieve Sawai Group standards moved forward through discussions and practical guidance.

Step-by-step preparations are steadily being made so that the company can manufacture pharmaceuticals that incorporate trust into each product.



Research and development

We carefully select only the best APIs from around the world, conduct product formulation research in order to achieve even higher quality, and conduct tests that guarantee the quality of developed formulations. We also actively demonstrate product ingenuity, the goal of which is to make products comfortable for patients to take and easy for healthcare professionals to handle.



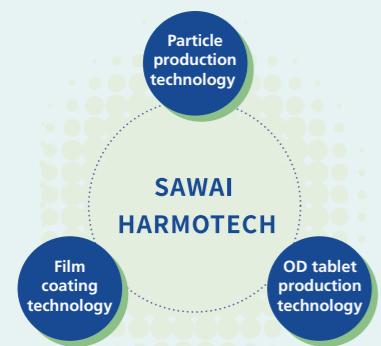
Research and development expenses	Number of R&D Division staff
¥12.5 billion Japan business	253 Sawai Pharmaceutical

Sawai's strengths

- Ability to undertake research and analysis of original drug patents
- Formulation technology capabilities based on human resources with expertise in API properties and formulation technology

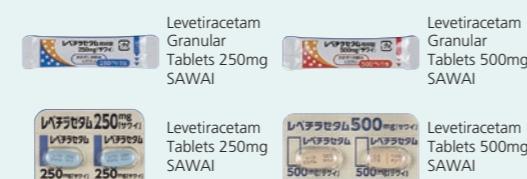
SAWAI HARMOTECH, Sawai Pharmaceutical's formulation technology

SAWAI HARMOTECH is the general name for Sawai Pharmaceutical's original formulation technologies that add value to medicines and create harmony in their formulation, such as technologies that make medicines more comfortable to take and the manufacturing of medicines more efficient.



Product ingenuity

In fiscal 2021, the Granular obtained approval for Levetiracetam Granular Tablets SAWAI and introduced the first granular tablet-form treatment for epilepsy. Out of consideration of the ingredient's bitterness and ease of taking, we employed a coating technology that uses moisture to add a gel coating to the tablet surface. Products come in three different forms, which include Levetiracetam tablets and DS, and this makes it possible to provide products that meet the needs of healthcare professionals and patients.



Procurement

Staff knowledgeable of items to be purchased select business partners who meet the Company's quality standards and closely work with them to achieve stable raw material procurement linked to sales forecasts and production plans. In order to achieve stable supply of raw materials, we have also built and maintain relations of trust by holding business partner explanatory meetings and working to continually evaluate business partners.



Sawai's strengths

- Procure a wide range of raw materials from around 500 companies in 30 countries throughout the world**
- Strong new product API research and procurement abilities
 - Selection and procurement of raw materials with primary emphasis on quality and safety
 - Use of multiple API sources to strengthen Procurement system stability

Sawai's strengths

- Strong new product API research and procurement abilities
- Selection and procurement of raw materials with primary emphasis on quality and safety
- Use of multiple API sources to strengthen Procurement system stability

Sales and marketing

Promptly delivering accurate information on products is an important aspect of the quality we offer. We provide information to patients and healthcare professionals through three channels—approximately 380 medical representatives (MRs); the Medical Information Center, an inquiry desk open 24 hours a day, 365 days a year; and a website.



Number of products on sale	Number of MRs
Approx. 800 Sawai Pharmaceutical	Approx. 380 Sawai Pharmaceutical
Approx. 130*	Approx. 40 Upsher-Smith
* Calculated according to the counting standards of Japan	

Sawai's strengths

- Provision of accurate information
- Extensive product lineup
- Strong ties with wholesalers and retailers