Research and development

Achieving first and
sole market launches thanks to
advanced formulation technology
and unique R&D system

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Formulation technology generated from field strengths: Value creation from expert talent and proprietary technology

The Sawai Group systematically cultivates and utilizes human resources with a high level of expertise in API properties and formulation technology. The high-level capability we possess as a result in formulation technology is our greatest strength. By collecting the latest information on APIs and formulations from around the world and promoting development in line with the International Council for Harmonisation (ICH), we are able to provide a stable supply of products that meet global quality standards.

In selecting APIs, we analyze their physical properties, quality, and stability, and use only those that meet our strict voluntary standards. Human resources with knowledge and experience in physical properties and quality select the most suitable APIs from Japan and overseas, demonstrating their analytical and evaluation capabilities from the early stages of product development.

The Group's formulation technology capabilities are supported by the insights and experience gained through the development of approximately 800 products. In the field, we take on new challenges on a daily basis. For example, in tablet development, where both masking of bitterness and stability are required, we have developed orally disintegrating (OD) tablets, which are not available with original drugs, by making full use of our proprietary technologies.

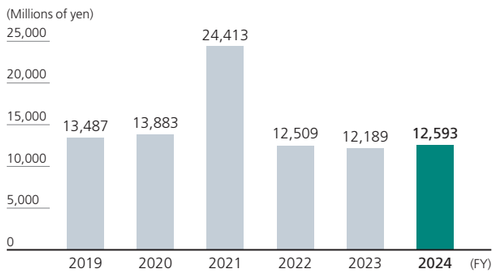
These proprietary technologies have been established as the SAWAI HARMOTECH®* system, consisting of nine core technologies, including nuclear particle manufacturing, rapid disintegration tablet manufacturing, and film coating. These are applied to many products and contribute to solving various issues such as formulation strength, disintegration, bitterness masking, and production efficiency.

The Group's formulation technologies are widely disseminated through seminars for pharmacists and feature pages on our corporate website, and our Group's technical capabilities in the field are highly regarded by healthcare professionals and the general public.

These efforts are supported by human resources with diverse expertise and broad insights in intellectual property, formulation technology, and physical property analysis. The Group fosters human resources through experiences in various departments within the Research & Development Division and takes cross-organizational action to promote advanced intellectual property strategies and formulation technology development. Furthermore, we are actively working to strengthen our R&D infrastructure by utilizing digital transformation (DX), collaborating with external research institutions, and studying physiological models that do not involve animal testing.

* For details, please see our website page on SAWAI HARMOTECH® (Japanese only).
https://www.sawai.co.jp/sawai_harmotech/

Research and development expenses



Note: Including impairment loss

Innovations for patients

Converting capsules to tablets
Large, hard-to-swallow capsules replaced with tablets

Miniaturizing tablets
Miniaturization of tablets that are large in size and difficult to swallow

Easy-to-swallow formulation
Modification to orally disintegrating (OD) tablets, gelatin formulations, etc.

Improved taste
Coatings, etc., to reduce bitterness

R&D process: An integrated system for quality and reliability

The Group's research and development process goes beyond the framework of a typical generic drug manufacturer and is characterized by a sophisticated system that combines unique intellectual property strategies, technological capabilities, and rigorous quality control. R&D begins with patent strategy planning and item selection, followed by multifaceted evaluation of IP risks and the potential of patent invalidation trials or patent circumvention, and seeks swift and steady product development and launch in cooperation with IP-specialized attorneys.

In formulation design and technology development, we utilize SAWAI HARMOTECH® to assess risk for bioequivalence, ensure stable supply, and create added value. We thoroughly manage data based on reliability standards at each research stage, with a system in place to support rigorous data checks by authorities when submitting applications for approval.

In addition, we have established a Good Manufacturing Practice (GMP) system in manufacturing investigational drugs so that they offer high quality, safety, and stability, and to scientifically verify their equivalence and reliability as generic drugs.

When applying for approval and launching products, applications are based on data in accordance with reliability standards and launches take place after regulatory review. Post-launch, we work to maintain and strengthen quality assurance and a stable supply system. Through these efforts, we aim to provide quality assurance for our products and ensure the trust of society.

Thus, the Group's R&D process, from intellectual property strategy to formulation design, data management, equivalence testing, and information dissemination, is structured to pursue quality and reliability in a consistent manner, which is the source of our R&D capability enabling us to achieve the first and sole market launch.

R&D process