

Analytical Science Protects the Safety of Our Food and Life

High Performance Liquid Chromatograph

Demands for Strict Quality Control

How dense is the active constituent of a pharmaceutical product? How much vitamin and calcium nutrition is there in food? Is the food we touch and eat free from harmful substances? These are only a few questions that are emerging as people are paying more attention to their health, safety, and environment. The government maintains the safe manufacturing and distribution of products by carrying out surprise inspections and imposing strict regulations. Now the demand of quality control of raw material is growing. Therefore, quality control and inspection in this area has been increased. Furthermore, correct and reproducible analysis data is important.

For example, there are many products made from chemicals such as daily products, electric appliances, vehicles, and other things we use in daily life. In this type of manufacturing business, we need to manufacture products in compliance with strict quality control regulations depending on the purpose of use, from raw materials to the final products. These manufacturing methods must comply with both domestic and international regulations. In accordance to The Pharmaceutical Affairs Law, we are obligated to gather and submit component data that focuses on the reproducibility of pharmaceutical products protecting people's health and cosmetic products being applied directly to the skin.

In recent years, more manufactured product components have become subject to regulation all over the world. Manufacturers must follow these regulations to market their products internationally. Our new issue now is how we can decrease inspection time to keep operation schedules on time.



Analzers that use the principle of Chromatography.



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To keep products safe for consumption, it is important for manufacturers to maintain high standards of quality control and therefore requires equipment capable of performing the ultra fast analysis. We have developed products designed for speedy analysis, reducing solvating media quantity consumed and electricity usage, and environment. We will continue listening to customers' voices to make a better product.

Upgrading Quality Control through Promotion of Streamlining of Analysis

Hitachi High-Technologies has developed a solution to the problem of inspection time. We provide a high performance liquid chromatograph that makes it possible to shorten the time of inspection while sustaining the correctness and reproducibility of the data. This method can be customized a variety of items such as pharmaceutical products, food, environmental analysis, chemistry and materials. To raise the analytical efficiency, analysis time has been decreased by up to one tenth of that of the conventional company products and made it possible to measure the reproducibility well with low light (=high sensitivity). The speed-up analysis adds conditions to examine various conditions, and improves not only productivity but the quality of the entire analysis. Also, to uphold our social responsibility for products, we have proven the basic performance attributed to the high-speed analyzer in reproducibility and stability through long duration tests. We continue to pursue quality, safety, and durability that follows the Hitachi Group's criteria of *Eco-Products. For example, we never use lead solders.

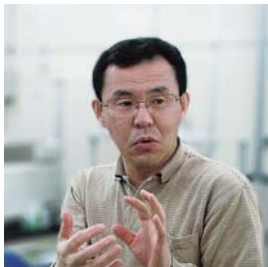
* Hitachi High-Technologies recognizes our environmentally sound products based on the common evaluation criteria among Hitachi Group known as "Eco-Product".

Practice Safety Criterion and Contribution to the Problem Solution for New Pharmaceutical Development Pharmacokinetic Analysis Service

Pharmacokinetic Analysis Contributing to the Pharmaceutical Products Development

Therapeutics for a variety of malignant diseases have been discovered through pharmaceutical and therapeutical progress. However, many patients still need valuable pharmaceutical products. Thus, pharmaceutical companies have new tasks designed for improving the accuracy of test results, regardless of the diversity and complexity of analytical work. These tasks are to confirm the safety and efficacy of clinical studies for new pharmaceutical development, to do post marketing survey, and to develop *generic drugs.

To assist in the completion of the tasks, Hitachi High-Tech Group offers our “pharmacokinetic analysis service”. Pharmacokinetics is one of the research fields that evaluates the efficacy and toxicity of medicine. We analyze blood, urine, nail and liver samples and report the results to the pharmaceutical companies or hospitals which requests our analysis service.



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Our company’s analyzer is capable of analyzing a very small quantity component such as a Pico unit (1/100 billionth).

It takes more than 10 years to develop new medicine, so it is necessary to manage data and keep security appropriately for a long-period data measurement and its follow up research.

We must pay the closest attention to the correctness and perfection of data and ensure facilities and test environments abide by the national safety criteria because the development of medicine is directly related to people’s lives.

Pharmacokinetic Analysis facilities ranked A in GLP. We receive a GLP adequateness inspection from the Pharmaceuticals and Medical Devices Agency every three years.



The Most Important Social Responsibility is Following Safety Criterion

It is necessary that we confirm to GLP (Good Laboratory Practice) on pharmaceutical development. This safety criterion was set up by the government for the research and development of pharmaceuticals and medical device. Our company strictly manages our facilities, technologies and quality to abide by GLP standards as we understand that conforming to the GLP is our social responsibility. We are making an effort to nourish highly knowledgeable and skilled employees who can conform to the GLP criteria. Along with following GLP standards, it is our standard to check and double check the correctness of all analyzed data and results.

Providing Knowledge and Information Data is Also an Important Role

We commonly have specialist discussions on the results of analysis with developers from pharmaceutical companies and offer them our technical and scientific expertise. We provide services that include our technology and analysis know-how making best use of our background experience as an analyzer maker. The end result is a huge amount of analyzed and collected data. Not only providing data quickly, we are working to arrange it and systematize effective utilization as a part of our services.

* branded generic drug sold after the patent of the new drug has expired with same component and lower cost.