Technology to Deliver Drugs Safely and Effectively to Target Sites

SANYO PRODUCT TOPICS

A Coating Agent for Solid Oral Dosage Forms: POLYQUID PA-30

Coating agents in solid oral doses are used to improve the functionality of these drugs. By applying a coating, these agents can improve swallowability, extend shelf life, and ensure the precise delivery of active ingredients to their target sites. We present a product designed to maximize drug efficacy.

Coating Agents are used in most solid oral drugs

Solid oral dosage forms, commonly referred to as solid oral drugs, are divided into three categories: tablets, granules, and capsules.

Typically, the active ingredients in these drugs are bitter and unpleasant to taste when taken directly, and are often sensitive to light, moisture, and oxygen. Therefore, coating agents are used to mask bitterness and odor, improve swallowability, enhance shelf-life, and add color. Coating agents play important roles in controlling the release of active ingredients in the body.

Drug Delivery Systems to Maximize Drug Efficacy

Oral drugs, such as food, are typically broken down in the stomach and absorbed into the body, primarily through the small intestine. By controlling the release of active ingredients in the "right amount," at the "right time," and to the "right place," therapeutic effects can be enhanced and side effects minimized. Such controlled release systems are known as drug delivery systems (DDS).

A DDS not only enhances the efficacy of drugs but also offers several advantages: it allows for the production of more medicines with fewer active ingredients, enabling more patients to be treated with limited active ingredients, and it can reduce costs, leading to more affordable treatments.

DDS have several control functions. One key function is "sustained release," which allows the drug to dissolve gradually in the body, reducing the frequency of doses and maintaining the required concentration for the required duration. This improves therapeutic outcomes.

Another function is "enteric solubility," which means that substances with this property dissolve in the intestine but not in the stomach, can effectively deliver active ingredients that are vulnerable to stomach acid to the small intestine, and can also reduce side effects, such as irritation caused by active ingredients that are harmful to the stomach.

In addition, advanced DDS, known as targeted delivery systems, are now utilized to concentrate active ingredients specifically on target cells, such as cancer cells, to minimize side effects as much as possible.

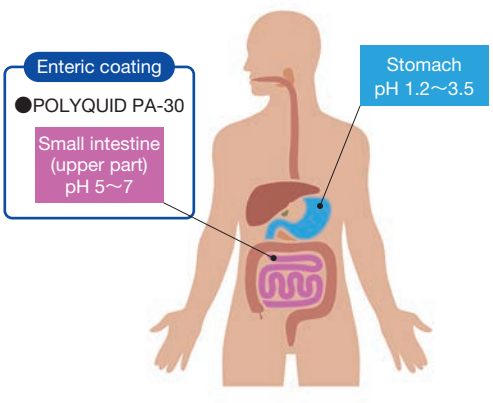
POLYQUID PA-30: Protecting Active Ingredients from Stomach Acid and Delivering Them Accurately to the Small Intestine

Among these, POLYQUID PA-30 is widely used as an enteric coating agent. Its main feature is its ability to dissolve in the small intestine without dissolving in the stomach. This feature protects the active ingredients from gastric acid and minimizes side effects in the stomach, while effectively delivering the active ingredients to the small intestine.

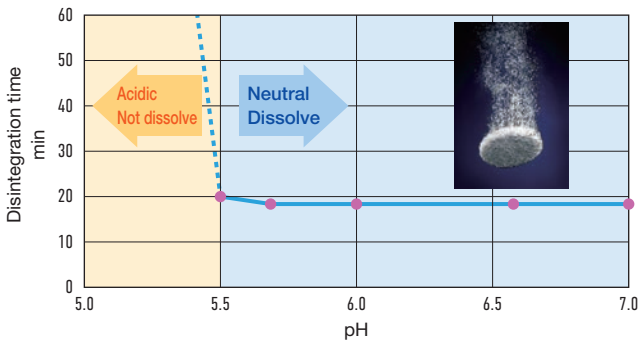
POLYQUID PA-30 was introduced by Sanyo Chemical in 2003. The enteric coating agents were mainly obtained from German manufacturers. We developed this product as a domestic alternative in response to requests from domestic pharmaceutical companies.

POLYQUID PA-30 is a copolymer composed of two monomers, ethyl acrylate and methacrylic acid. It is classified as a "pH-responsive polymer," which means that its solubility changes with pH. It does not dissolve in the gastric juices of stomach with a pH of 1.2 to 3.5 but dissolves in the intestinal juices with a pH of 5 to 7. Consequently, coating active ingredients with this polymer ensures efficient delivery to the intestine.

Because of these properties, POLYQUID PA-30



■Relationship between pH and disintegration time (in McIlvain buffer)



is used as a coating agent for various drugs, including acid-sensitive ulcer treatments and analgesics, which can cause stomach irritation.

In terms of safety, an essential requirement for pharmaceutical excipients is that they be water-dispersed products that are free of organic solvents and do not use biologically derived raw materials. It also meets stringent standards for manufacturing facilities and quality control, thereby ensuring a highly reliable and stable supply.

Providing Affordable Medicines Consistently to People Around the World

POLYQUID PA-30 complies with the Japanese Pharmaceutical Excipients standards (JPE) as well as the United States and European Pharmacopoeias (USP-NF, EP), making it suitable for global use. By providing affordable medicines consistently, POLYQUID PA-30 has contributed to the achievement of SDGs Goal3, "Good Health and Well-Being for All." Sanyo Chemical continues to expand the use of POLYQUID PA-30 to other countries worldwide, including developing countries, to achieve this goal.

Since low-molecular-weight drugs were the main focus until recently, pharmaceutical excipients were also mainly targeted at them; however, with the development of a wide range of drugs, including high-molecular-weight drugs such as antibody drugs and medium-molecular-weight drugs such as peptides and nucleic acids, new pharmaceutical excipients are needed. Furthermore, there are urgent needs to address issues such as improving quality of life and reducing medical costs, and the needs for DDS are predicted to continue to diversify and accelerate in the future.

Sanyo Chemical has not only established POLYQUID PA-30 but also a number of pharmaceutical-related products such as the MACROGOL series, and is also developing products based on them that can respond to new needs. In the future, we will continue to contribute to the health and quality of life of people worldwide by proposing optimal formulations that combine these products and by developing new technologies.

■Product Information of POLYQUID PA-30

Appearance	Solid content %	Solubility pH	Applicable regulatory requirements	Main use (Notes)
Emulsion	30	≧5.5	<JPE>Methacrylic Acid Copolymer LD <USP-NF>Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion <EP>Methacrylic Acid-Ethyl Acrylate Copolymer(1:1) Dispersion 30 Per Cent As mentioned above, it complies with three pharmacopoeias, POLYQUID PA-30 is also registered with the U.S. Food and Drug Administration (FDA) Drug Master File (DMF) under the name POLYQUID PA-30.	Enteric Coating (US DMF 16349)

Please contact our company's sales representative when handling our products.
Please also refer the "Safety Data Sheet" (SDS) in advance.
It is the responsibility of the user to determine its suitability and safety for the intended use.