

# **Pharmaceutical Dissolution Testing Services Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Services Method (In vitro, In vivo), By Dissolution Apparatus (Basket, Paddle, Others), By Dosage Form (Capsule, Tablets, Others) By Region and Competition**

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## **Abstracts**

Global Pharmaceutical Dissolution Testing Services Market has valued at USD 650.18 Million in 2022 and is anticipated to project robust growth in the forecast period with a CAGR of 8.33% through 2028. The pharmaceutical industry is witnessing significant growth in the demand for dissolution testing services, driven by the increasing emphasis on drug quality, regulatory compliance, and the pursuit of more effective and reliable medications. Pharmaceutical dissolution testing services have become a cornerstone in ensuring the safety and efficacy of pharmaceutical products, and their market is poised for steady expansion. Pharmaceutical dissolution testing services play a critical role in the development and quality control of medications, ensuring that they deliver the intended therapeutic effects to patients. Dissolution testing is a vital step in the pharmaceutical industry, providing valuable insights into a drug's release rate, bioavailability, and performance in the human body. Dissolution testing is a laboratory technique used to determine how quickly and completely a solid dosage form, such as a tablet or capsule, dissolves in a specific liquid medium. This process simulates the drug's behavior when ingested, helping pharmaceutical companies understand its performance in the human body. The results of these tests are essential for regulatory compliance, product formulation, and batch-to-batch consistency. These services ensure that medications meet strict quality standards. By monitoring dissolution profiles, pharmaceutical companies can identify and rectify issues related to formulation, manufacturing processes, and raw materials, guaranteeing the safety and efficacy of the final product.

Dissolution testing is a regulatory requirement in many countries.

Pharmaceutical companies must provide dissolution data to regulatory authorities as part of the drug approval process. Compliance with these regulations is essential to bringing new medications to the market. Pharmaceutical dissolution testing services enable companies to maintain consistent product quality across different batches. By regularly testing samples, they can identify and address variations that might affect the drug's performance. Dissolution testing helps researchers fine-tune drug formulations for optimal performance. It allows them to assess the impact of excipients and other ingredients on drug release, bioavailability, and overall effectiveness. During drug development, dissolution testing guides decisions about dosage forms, release mechanisms, and formulation strategies. It ensures that the medication delivers the desired therapeutic effect in a reliable and predictable manner. Identifying formulation or manufacturing issues early in the development process can save pharmaceutical companies significant time and resources. Avoiding costly recalls and production delays is crucial for business sustainability.

## Key Market Drivers

### Rising Pharmaceutical R&D

The pharmaceutical industry continues to invest heavily in research and development to bring innovative drugs to market. Dissolution testing services play a pivotal role in drug development by helping researchers optimize formulations, evaluate bioavailability, and ensure batch-to-batch consistency. The pharmaceutical sector has always been at the forefront of innovation, with a primary goal of developing safe and efficacious drugs to address a wide array of health conditions. In recent years, this drive has intensified, fueled by the pressing need to address diseases, health crises, and emerging pathogens. As a result, pharmaceutical R&D expenditure has soared, encompassing everything from novel therapies to improved drug delivery systems and complex biologics. This expansion of R&D horizons has led to an influx of new drug candidates entering the development pipeline. However, it has also brought about new challenges related to understanding and optimizing the behaviour of these candidates in the human body. This is where pharmaceutical dissolution testing services come into play.

Pharmaceutical dissolution testing is a critical tool that allows researchers to assess how a drug formulation behaves when ingested. It provides insights into the drug's release rate, bioavailability, and overall performance. Essentially, dissolution testing simulates what happens to the drug within the human body, helping scientists fine-tune

formulations and optimize drug delivery methods. With the increasing complexity of drug candidates, including biopharmaceuticals and nanoparticle-based formulations, understanding their dissolution behavior is paramount. This understanding is crucial not only for regulatory compliance but also for ensuring that these advanced medicines effectively reach their intended targets within the body. Pharmaceutical dissolution testing is not merely a matter of choice for drug developers; it is often a regulatory requirement. Regulatory agencies like the FDA and EMA mandate that pharmaceutical companies provide dissolution data as part of the drug approval process. These agencies require evidence that a medication consistently performs as intended, ensuring both safety and efficacy for patients. As the pharmaceutical R&D landscape becomes increasingly competitive and complex, many companies are turning to specialized service providers for dissolution testing. These contract research organizations (CROs) have the expertise, state-of-the-art equipment, and regulatory knowledge to offer comprehensive testing services.

### Growing Drug Manufacturing

As the global population grows and ages, the demand for pharmaceutical products increases. This surge in drug manufacturing drives the need for quality control measures, including dissolution testing, to guarantee that medications meet safety and efficacy standards. One of the primary factors fueling the expansion of drug manufacturing is the increasing global demand for pharmaceutical products. The world's population is growing, aging, and becoming more health-conscious, leading to greater demand for a wide range of medications. Whether it's essential medicines to combat common diseases, specialized treatments for rare conditions, or innovative therapies to address unmet medical needs, pharmaceutical companies are facing growing pressure to produce pharmaceuticals at an unprecedented scale. In the pharmaceutical industry, maintaining product quality and ensuring regulatory compliance are non-negotiable imperatives. With more medications in production, there's a greater need for robust quality control measures throughout the manufacturing process. This is where pharmaceutical dissolution testing services come into play.

Pharmaceutical dissolution testing is a key component of quality control. It involves assessing how solid dosage forms, such as tablets and capsules, dissolve in a specific liquid medium, simulating what happens when patients ingest the medication. This testing provides critical data on a drug's release rate, bioavailability, and overall performance, ensuring that it meets regulatory standards and delivers the intended therapeutic effects. Pharmaceutical dissolution testing is not optional but a regulatory requirement in many countries. Regulatory agencies like the U.S. Food and Drug

Administration (FDA) and the European Medicines Agency (EMA) demand dissolution data as part of the drug approval process. Compliance with these regulations is essential for pharmaceutical companies looking to market their products globally.

## Regulatory Mandates in Emerging Markets

As pharmaceutical markets expand in emerging economies, regulatory authorities in these regions are increasingly aligning their requirements with international standards. This includes mandating dissolution testing as part of the drug approval process. The harmonization of regulatory requirements between established and emerging markets further amplifies the demand for dissolution testing services. Pharmaceutical companies seeking to access these burgeoning markets must ensure that their products meet the requisite dissolution specifications, driving the need for comprehensive testing services. Emerging markets have emerged as hotbeds of pharmaceutical growth, driven by factors such as rising populations, improved access to healthcare, and an increasing burden of disease. Countries in Asia, Latin America, and Africa are experiencing a surge in pharmaceutical production, aiming to meet the healthcare needs of their populations and tap into global pharmaceutical markets. As the pharmaceutical industry expands in these regions, there is a growing emphasis on ensuring that the drugs produced meet the highest quality and safety standards. This is where regulatory mandates come into play, aligning the practices of emerging markets with those of established pharmaceutical players.

In many emerging markets, regulatory mandates now require pharmaceutical companies to conduct dissolution testing as part of the drug approval process. These mandates emphasize the need for pharmaceutical manufacturers to provide comprehensive data on how their products behave within the human body. Dissolution testing helps ensure that medications consistently meet quality and performance specifications, regardless of the market they are destined for. It serves as a gatekeeper, allowing only formulations that meet dissolution criteria to proceed through the development pipeline and reach patients. Moreover, dissolution testing is instrumental in maintaining batch-to-batch consistency during manufacturing, a vital factor in pharmaceutical production. By regularly testing samples from various production batches, manufacturers can detect variations in dissolution profiles and make necessary adjustments to guarantee product reliability.

## Complex Drug Formulations and Biopharmaceuticals

The pharmaceutical landscape is witnessing a surge in complex drug formulations,

including long-acting injectables, liposomal formulations, and nanoparticle-based drug delivery systems. Additionally, biopharmaceuticals, such as monoclonal antibodies and gene therapies, have become pivotal in treating various diseases. These innovative drug formulations pose unique challenges in understanding their dissolution behavior. Pharmaceutical dissolution testing services are evolving to cater to these complexities, with customized testing protocols tailored to assess the release and performance of these specialized medications. Pharmaceutical dissolution testing is a linchpin in the development and quality control of complex drug formulations. It involves assessing how a drug formulation dissolves in a specific liquid medium, simulating the conditions within the human body. This testing provides critical insights into the release rate, bioavailability, and overall performance of these novel formulations. Liposomes are microscopic vesicles that can encapsulate drugs, enabling targeted delivery and controlled release. These formulations are particularly valuable for drugs with low solubility or those requiring precise release profiles. Nanoparticles, often engineered using materials like polymers or lipids, can carry therapeutic agents to specific sites within the body. These systems enhance drug solubility, bioavailability, and therapeutic precision.

Long-acting injectable formulations allow for sustained drug release over an extended period. These formulations are advantageous for improving patient adherence and reducing dosing frequency. Thin oral films and dissolvable tablets offer convenient alternatives to traditional oral dosage forms. They dissolve rapidly in the mouth, allowing for quick drug absorption and avoiding the need for water. For liposomal formulations, nanoparticles, and long acting injectables, dissolution testing helps researchers determine how quickly and to what extent the drug is released from the carrier system. This information is essential for optimizing formulation parameters and ensuring that the medication delivers the intended therapeutic effect. Additionally, oral films and dissolvable tablets rely on rapid dissolution for their effectiveness. Dissolution testing enables pharmaceutical companies to fine-tune these formulations to achieve the desired rate of disintegration and drug release.

## Key Market Challenges

### Regulatory Compliance

One of the most significant challenges facing the pharmaceutical dissolution testing services market is the stringent regulatory landscape. Regulatory bodies like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have stringent guidelines and requirements for pharmaceutical testing. These guidelines are

continuously evolving, making it challenging for testing laboratories to keep up with the latest compliance standards. Compliance with these regulations is not only mandatory but also essential for ensuring the safety and efficacy of pharmaceutical products. Failure to meet regulatory standards can result in product recalls, legal repercussions, and damage to a company's reputation. Consequently, testing laboratories must invest heavily in training, equipment, and documentation to ensure they are in line with the latest regulatory requirements.

### Cost-Effective Testing

Pharmaceutical dissolution testing can be an expensive process, particularly when performed by third-party testing services. The cost of reagents, equipment, and skilled personnel adds up quickly, making it challenging for pharmaceutical companies to strike a balance between cost-effectiveness and quality testing. Companies often face the dilemma of choosing between in-house testing, which may require significant capital investment, or outsourcing to testing services, which can be expensive. The challenge here is to find cost-effective solutions that do not compromise the quality and accuracy of dissolution testing. Innovations in automation, data analysis, and equipment can help mitigate these cost challenges, but it remains a pressing issue for the pharmaceutical dissolution testing services market.

### Data Management and Analysis

Pharmaceutical dissolution testing generates vast amounts of data, and effectively managing and analyzing this data is a significant challenge. Laboratories must invest in robust data management systems to store, retrieve, and interpret test results accurately. Furthermore, data integrity and traceability are crucial in pharmaceutical testing, as any errors or inconsistencies can have severe consequences. Additionally, the interpretation of dissolution test results requires expertise and a deep understanding of pharmaceutical science. Laboratories must employ skilled scientists and analysts who can translate raw data into meaningful insights for drug manufacturers. The shortage of trained professionals in this field adds to the challenges faced by the pharmaceutical dissolution testing services market.

### Key Market Trends

#### Increasing Drug Development Activities

The pharmaceutical industry is witnessing a surge in drug development activities, driven

by growing healthcare needs and advancements in biotechnology and pharmacology. As pharmaceutical companies expand their pipelines to address various medical conditions, the demand for dissolution testing services has escalated. Dissolution testing is integral during the drug development process, aiding in formulation development, quality control, and regulatory submissions. The rise in drug development activities is consequently boosting the demand for dissolution testing services, as companies seek specialized expertise to navigate complex testing protocols and ensure regulatory compliance. Modern drug formulations are becoming increasingly complex, with advancements such as controlled-release formulations, nanoparticles, and biologics. These intricate formulations require sophisticated dissolution testing procedures to evaluate their performance accurately. Pharmaceutical companies turn to specialized testing services to navigate these complexities.

Regulatory bodies like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require rigorous testing throughout the drug development process. Meeting these stringent regulatory requirements necessitates the expertise of dissolution testing services providers. They play a pivotal role in helping pharmaceutical companies navigate the complex landscape of regulatory compliance. Drug development is an expensive and time-consuming process. Outsourcing dissolution testing to specialized service providers can help pharmaceutical companies save both time and costs. This trend has been further accentuated by the increased focus on cost-efficiency within the pharmaceutical industry.

### Growing Popularity of Generic Drugs

The global demand for generic drugs continues to rise, driven by their cost-effectiveness compared to branded counterparts. Generic drug manufacturers must demonstrate bioequivalence to the reference listed drug (RLD) through dissolution testing, which has become a crucial part of their regulatory submissions. This trend has led to a significant uptick in demand for dissolution testing services. Pharmaceutical companies and generic drug manufacturers alike rely on dissolution testing services providers to ensure their products meet the required quality standards and demonstrate bioequivalence. As the generic drug market continues to expand, the pharmaceutical dissolution testing services market is set to benefit from sustained growth.

Generic drug manufacturers must demonstrate bioequivalence to the reference listed drug (RLD) through rigorous testing, including dissolution testing. Bioequivalence ensures that a generic drug performs in the same manner as the brand-name counterpart. Pharmaceutical dissolution testing services play a critical role in helping

generic drug manufacturers meet these stringent requirements. They assist in validating the equivalence of generic products, ensuring that they are safe and effective alternatives. Regulatory bodies like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) impose stringent quality standards on generic drugs. To gain approval, generic drug manufacturers must adhere to these regulations, which often include comprehensive dissolution testing. The demand for dissolution testing services has surged as generic drug companies strive to meet these compliance standards.

## Segmental Insights

### Method Insights

Based on the method, the in-vitro method segment emerged as the dominant player in the global market for Pharmaceutical Dissolution Testing Services in 2022. This remarkable growth can be attributed to several factors including regulatory compliance, accuracy and precision, cost efficiency, etc. The pharmaceutical industry operates in a heavily regulated environment, with stringent requirements for drug testing and approval. In-vitro dissolution testing is a well-established and widely accepted method for assessing the release of drug compounds from formulations. Regulatory bodies like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) often prefer and mandate in-vitro methods due to their reliability and consistency in meeting regulatory compliance standards.

### Dosage Form Insights

Based on the Dosage Form, tablet segment emerged as the dominant player in the global market for Pharmaceutical Dissolution Testing Services in 2022. This remarkable dominance can be attributed to several compelling factors that underscore the preference for tablet formulations in pharmaceutical testing. First and foremost, tablets are one of the most widely used and preferred dosage forms in the pharmaceutical industry. Their popularity can be attributed to their ease of manufacturing, stability, and patient-friendly administration.

### Regional Insights

North America emerged as the dominant player in the global Pharmaceutical Dissolution Testing Services market in 2022, holding the largest market share. This is on account of its advanced healthcare infrastructure, strong adoption of technology, and



robust research and development activities. North America, particularly the United States, is home to state-of-the-art pharmaceutical research and testing facilities. The availability of advanced dissolution testing equipment and technology in the region ensures precision, accuracy, and efficiency in testing services.

### Key Market Players

Intertek Group Plc

Avivia BV

Almac Group

Agilent Technologies, Inc.

Catalent, Inc.

ThermoFisher Scientific Inc

Charles River Laboratories

Cambrex

Boston Analytical

Pace Analytical Life Sciences

### Report Scope:

In this report, the Global Pharmaceutical Dissolution Testing Services Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

#### Pharmaceutical Dissolution Testing Services Market, By Services Method:

In vitro

In vivo

Pharmaceutical Dissolution Testing Services Market, By Dosage Form:

Capsule

Tablets

Others

Pharmaceutical Dissolution Testing Services Market, By Dissolution Apparatus:

Basket

Paddle

Others

Pharmaceutical Dissolution Testing Services Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Kuwait

Turkey

Egypt

## Competitive Landscape

**Company Profiles:** Detailed analysis of the major companies present in the Global Pharmaceutical Dissolution Testing Services Market.

### Available Customizations:

Global Pharmaceutical Dissolution Testing Services market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

#### Company Information

Detailed analysis and profiling of additional market players (up to five).

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