

Global Pharmaceutical Release Testing Market Growth (Status and Outlook) 2026-2032

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Abstracts

The global Pharmaceutical Release Testing market size is predicted to grow from US\$ 2777 million in 2025 to US\$ 4313 million in 2032; it is expected to grow at a CAGR of 6.5% from 2026 to 2032.

Pharmaceutical Release Testing refer to outsourced or contract laboratory services performed under GMP, cGMP or equivalent quality systems to verify that pharmaceutical materials, drug substances, drug products, clinical trial materials and commercial production lots conform to approved specifications before quality release.

Pharmaceutical Release Testing should be viewed as a mandatory quality-control service embedded in the pharmaceutical supply chain rather than as a single analytical method. For conventional small-molecule drugs, the service is largely built around compendial methods, chromatography, assay, impurities, dissolution, water content and microbiological limits. For biologics and complex modalities, however, release testing becomes a multi-platform quality package involving potency, purity, identity, residual host-cell proteins, residual DNA, viral safety, mycoplasma, sterility, endotoxin and other safety-related assays. The regulatory foundation of the market is strong because cGMP and GMP frameworks require batch-level quality evaluation before release, while ICH specifications define the combination of tests, analytical procedures and acceptance criteria used to judge product quality. As a result, the market has a recurring and compliance-driven demand base, but its growth rate depends heavily on drug modality mix, commercial batch volume, clinical pipeline activity and the degree of outsourcing by pharmaceutical sponsors.

From the supply side, the industry is structured around four major provider groups: global TIC laboratory networks, specialist biologics and biosafety testing platforms,

CDMO-integrated QC laboratories, and regional GMP laboratories. Global players such as Eurofins, SGS and Intertek benefit from broad laboratory networks and multi-category testing capabilities. Specialist platforms such as Charles River, BioReliance and Sartorius BioOutsource hold stronger positions in biologics lot release, viral safety and biosafety testing. CDMO and CRDMO groups such as Thermo Fisher/PPD, Catalent, Lonza, Samsung Biologics, WuXi AppTec and WuXi Biologics integrate release testing with process development, manufacturing, stability programs and regulatory support. This explains why the broad longlist is materially larger than the core formal list: many companies perform analytical or QC work, but only a subset has clear official evidence of external GMP release testing, meaningful laboratory infrastructure and repeatable service positioning.

Demand growth is increasingly driven by complex drug modalities and supply-chain changes. Biologics, ADCs, bispecifics, vaccines, mRNA products, oligonucleotides, peptides and cell and gene therapies increase both the number of required assays and the technical intensity per lot. Emerging biotech companies and virtual pharmaceutical companies tend to outsource CMC and release testing earlier in development, while larger pharmaceutical companies use qualified third-party laboratories to build redundancy, regional flexibility and inspection-ready documentation. Growth is also supported by sterile manufacturing, injectable capacity expansion, high-potency drugs and complex delivery systems. Future competition will therefore not be determined only by price. It will increasingly depend on method validation speed, data integrity, regulatory inspection track record, cross-region service coverage, biologics and CGT assay depth, and the provider's ability to coordinate release testing with manufacturing and stability programs.

From an industry evolution perspective, consolidation and capital deployment are reshaping the market. Large life-science service providers and CDMOs continue to expand analytical testing capacity through acquisitions, internal laboratory investment and integrated CMC service models. Catalent's acquisition by Novo Holdings is an example of how strategic manufacturing and analytical service assets are being repositioned within broader pharmaceutical supply networks. Regionally, North America and Europe remain the strongest bases for regulatory experience, biologics testing and global customers. China and India are expanding quickly through CRDMO ecosystems and cost-efficient CMC platforms, while Japan and South Korea are more concentrated around high-quality regional CDMO and biologics manufacturing platforms. The outlook remains positive, but low-complexity compendial testing is likely to face stronger price competition and automation, while high-complexity biologics, sterile, cell and gene therapy, nucleic-acid drug and impurity-control testing will remain the most attractive

growth segments.

LPI (LP Information)' newest research report, the 'Pharmaceutical Release Testing Industry Forecast' looks at past sales and reviews total world Pharmaceutical Release Testing sales in 2025, providing a comprehensive analysis by region and market sector of projected Pharmaceutical Release Testing sales for 2026 through 2032. With Pharmaceutical Release Testing sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world Pharmaceutical Release Testing industry.

This Insight Report provides a comprehensive analysis of the global Pharmaceutical Release Testing landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on Pharmaceutical Release Testing portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global Pharmaceutical Release Testing market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Pharmaceutical Release Testing and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Pharmaceutical Release Testing.

This report presents a comprehensive overview, market shares, and growth opportunities of Pharmaceutical Release Testing market by product type, application, key players and key regions and countries.

Segmentation by Type:

Identity and Assay Testing

Purity and Impurity Testing

Potency and Bioactivity Testing

Others

Segmentation by Testing Technology Principles:

Chromatographic Testing

Spectroscopic Testing

Biological Testing

Segmentation by Service Model:

One-Time Batch Release Testing

Annual Contract Release Testing

Others

Segmentation by Application:

Chemical Pharmaceutical Industry

Biopharmaceutical Industry

Cell and Gene Therapy Industry

Others

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

Eurofins Scientific SE

Thermo Fisher Scientific

Merck KGaA

Charles River Laboratories

SGS SA

Catalent, Inc.

WuXi AppTec

Intertek Group plc

Labcorp Holdings

Samsung Biologics

Lonza Group AG

Pace Analytical Life Sciences

Frontage Laboratories

Curia Global

Cambrex

Alcami

Nelson Laboratories

Element Materials Technology

CMIC Holdings

Sumika Chemical Analysis Service

Tentamus Group

Syngene International

Aragen Life Sciences

RSSL

Nuvisan

Pharmaron

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