+357 96 030922
info@marketpublishers.com

Extractable & Leachable Testing Services Market - Global Industry Size, Share, Trends, Opportunity and Forecast, Segmented By Product Tested (Container Materials/ Packaging, Single-Use, Medical Devices, Biopharmaceuticals/ Biologicals, Others), By Technique (Spectrometry, Spectroscopy, Total Organic Carbon, Conductivity, Others), By Region & Competition, 2021-2031F

https://marketpublishers.com/r/E71600902753EN.html
Date: January 2026
Pages: 180
Price: US$ 4,500.00 (Single User License)
ID: E71600902753EN

Abstracts

The Global Extractable & Leachable Testing Services Market is projected to expand from USD 2.27 Billion in 2025 to USD 4.76 Billion by 2031, registering a CAGR of 13.13%. These services focus on analytically assessing chemical migration from container closure systems, medical devices, and processing equipment into pharmaceutical products to guarantee patient safety. The sector is chiefly propelled by strict health authority regulations governing drug-container interactions and the increasing prominence of biologics, which are notably sensitive to packaging materials. Sector expansion is further bolstered by significant capital investment in innovation; for instance, the European Federation of Pharmaceutical Industries and Associations reported that the pharmaceutical industry allocated an estimated ?55,000 million to research and development in Europe in 2024, leveraging these services to validate novel therapies.

However, a major obstacle hindering market growth is the absence of globally harmonized regulatory standards for specific testing protocols. Inconsistent guidelines across various geographic regions generate compliance difficulties for manufacturers, frequently requiring redundant testing procedures. This lack of uniformity elevates

+357 96 030922
info@marketpublishers.com

operational expenses and slows down the international commercialization of pharmaceutical products.

Market Driver

The rapid growth of the biopharmaceutical industry and its biologics pipeline serves as a major driver for the extractable and leachable testing services market. As the sector transitions toward complex large-molecule therapies, rigorous safety assessments of container closure systems are essential to prevent product contamination. This wave of innovation is highlighted by regulatory milestones; the U.S. Food and Drug Administration's "Advancing Health Through Innovation: New Drug Therapy Approvals 2023" report from January 2024 noted the approval of 55 novel drugs, all requiring thorough compatibility studies. To sustain these expansive pipelines, manufacturers are investing heavily in production infrastructure that necessitates extensive validation; for example, Novo Nordisk announced in a June 2024 press release a commitment of 4.1 billion USD to construct a new fill and finish facility in North Carolina, directly fueling the demand for material qualification.

Simultaneously, the strategic move toward outsourcing analytical testing to specialized Contract Research Organizations (CROs) is notably shaping market dynamics. Pharmaceutical firms are increasingly depending on external partners to utilize high-sensitivity trace impurity detection technologies, avoiding the need for capital-intensive internal laboratories. This outsourcing approach allows sponsors to manage compliance complexities efficiently while concentrating on core development stages. The financial performance of service providers illustrates this reliance; in its "Third Quarter 2024 Results" release from October 2024, Medpace Holdings, Inc. reported revenue of 533.3 million USD, an 8.3% year-over-year rise. Such consistent growth among CROs highlights their critical function in conducting mandatory safety testing for global product commercialization.

Market Challenge

The absence of global regulatory harmonization regarding specific testing protocols poses a major limitation on the efficiency and expansion of the Extractable and Leachable Testing Services Market. With regulatory bodies in different jurisdictions enforcing varying safety guidelines, manufacturers are forced to conduct duplicative testing to meet each unique requirement. This fragmentation hinders testing laboratories from standardizing their assessment methods, resulting in greater operational complexity and increased costs for pharmaceutical clients seeking

+357 96 030922
info@marketpublishers.com

international product distribution.

As a result, these regulatory inconsistencies extend drug approval timelines, delaying the global market entry of therapeutics. The financial toll of these compliance barriers is significant within the wider scope of drug development. According to the Pharmaceutical Research and Manufacturers of America, member companies invested roughly $103 billion in research and development in 2024, a vast expenditure driven in part by the need to manage complex and non-uniform regulatory safety assessments. This repetitive validation process drains resources that could otherwise support market expansion, thereby impeding the overall momentum of the testing services sector.

Market Trends

The growing emphasis on characterizing cell and gene therapy products is fundamentally altering the technical demands for extractable and leachable studies. Unlike conventional therapeutics, these advanced modalities frequently employ viral vectors and rely on complex single-use manifolds, requiring strict evaluation of polymeric components to avoid toxicity or immunogenicity caused by leachates. This heightened attention to material safety correlates directly with the sector's strong financial backing; the Alliance for Regenerative Medicine's "State of the Industry Briefing" in January 2025 noted that global investment in the cell and gene therapy sector hit $15.2 billion in 2024. Such substantial capital speeds up the development pipeline, forcing testing laboratories to implement specialized protocols to detect trace leachables that might jeopardize the stability of these high-value biologics.

Concurrently, the market is seeing a notable rise in E&L testing for novel drug delivery and combination products, spurred by the trend toward patient-centric self-administration devices. Combining pharmaceuticals with medical devices like pre-filled syringes, auto-injectors, and wearable pumps places new materials, such as rubber plungers and silicone oil lubricants, in direct contact with the drug, necessitating thorough interaction studies. This trend is supported by increasing delivery system production; in August 2024, Schott Pharma reported in its "Schott Pharma delivers strong third quarter results" press release that its Drug Delivery Systems segment saw a 39% year-over-year revenue increase. This swift growth in device manufacturing requires extensive extractable profiling to ensure compliance with combination product regulations, thereby maintaining demand for advanced analytical testing services.

Key Market Players

+357 96 030922
info@marketpublishers.com

Eurofins Scientific SE

SGS SA

Intertek Group plc

WuXi AppTec

Merck KGaA

West Pharmaceutical Services, Inc.

Boston Analytical

Medical Engineering Technologies Ltd.

Nelson Laboratories, LLC

Pace Analytical Services, LLC

Report Scope

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

Extractable & Leachable Testing Services Market, By Product Tested

Container Materials/ Packaging

Single-Use

Medical Devices

Biopharmaceuticals/ Biologicals

Others

+357 96 030922
info@marketpublishers.com

Extractable & Leachable Testing Services Market, By Technique

- Spectrometry
- Spectroscopy
- Total Organic Carbon
- Conductivity
- Others

Extractable & Leachable Testing Services Market, By Region

- North America
  - United States
  - Canada
  - Mexico
- Europe
  - France
  - United Kingdom
  - Italy
  - Germany
  - Spain
- Asia Pacific
  - China
  - India

+357 96 030922
info@marketpublishers.com

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Extractable & Leachable Testing Services Market.

Available Customizations:

Global Extractable & Leachable Testing Services Market report with the given market data, TechSci 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).

+357 96 030922
info@marketpublishers.com

Contents

+357 96 030922
info@marketpublishers.com

6. NORTH AMERICA EXTRACTABLE & LEACHABLE TESTING SERVICES MARKET OUTLOOK

7. EUROPE EXTRACTABLE & LEACHABLE TESTING SERVICES MARKET OUTLOOK

+357 96 030922
info@marketpublishers.com

8. ASIA PACIFIC EXTRACTABLE & LEACHABLE TESTING SERVICES MARKET OUTLOOK

+357 96 030922
info@marketpublishers.com

9. MIDDLE EAST & AFRICA EXTRACTABLE & LEACHABLE TESTING SERVICES

+357 96 030922
info@marketpublishers.com

MARKET OUTLOOK

10. SOUTH AMERICA EXTRACTABLE & LEACHABLE TESTING SERVICES MARKET OUTLOOK

+357 96 030922
info@marketpublishers.com

+357 96 030922
info@marketpublishers.com

15. COMPETITIVE LANDSCAPE

16. STRATEGIC RECOMMENDATIONS

17. ABOUT US & DISCLAIMER

+357 96 030922
info@marketpublishers.com

I would like to order

Product name: Extractable & Leachable Testing Services Market - Global Industry Size, Share, Trends, Opportunity and Forecast, Segmented By Product Tested (Container Materials/ Packaging, Single-Use, Medical Devices, Biopharmaceuticals/ Biologicals, Others), By Technique (Spectrometry, Spectroscopy, Total Organic Carbon, Conductivity, Others), By Region & Competition, 2021-2031F

Product link: https://marketpublishers.com/r/E71600902753EN.html

Price: US$ 4,500.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:
info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page https://marketpublishers.com/r/E71600902753EN.html