

Extractable And Leachable Testing Services Market Size, Share & Trends Analysis Report By Product Type (Container Closure Systems, Drug Delivery Systems), By Application (Parenteral Drug Products, Ophthalmic), By Region, And Segment Forecasts, 2025 - 2033

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Abstracts

The global extractable and leachable testing services market size was estimated at USD 1.13 billion in 2024 and is expected to reach USD 3.57 billion by 2033, growing at a CAGR of 14.3% from 2025 to 2033. The expanding pharmaceutical and biotechnology sectors across the world are fueling the demand for E&L testing services.

Moreover, increasing regulatory scrutiny on the quality of healthcare products, the rise of complex drug formulations, such as biologics and combination products, and rising emphasis on product safety are further anticipated to propel the market growth. The COVID-19 pandemic had positively impacted extractable and leachable testing services. With the heightened focus on healthcare and pharmaceuticals during the pandemic, there has been an increased awareness of the importance of rigorous testing to ensure the safety and efficacy of medical products. As a result, extractable and leachable testing services have gained more recognition and investment, leading to advancements in testing methodologies, equipment, and expertise. The pharmaceutical and medical device industries have been able to accelerate their research and development efforts to deliver innovative products while maintaining a strong commitment to safety and compliance. According to a WHO article, nearly 16 billion vaccine doses worth USD 141 billion were supplied in 2021, nearly thrice the market volume of 2019 (5.8 billion) and nearly three-and-a-half times the market value of 2019 (USD 38 billion). Thus, the increased demand for vaccines during the pandemic

boosted the demand for extractable and leachable testing services.

The pharmaceutical and biotechnology industry has been rapidly growing in recent years due to advancements in technology, increased demand for novel drugs, and a growing incidence & prevalence of chronic diseases. This has also led to increased R&D activities for the creation of novel therapeutics. For instance, in 2022, the U.S. FDA's Center for Drug Evaluation and Research (CDER) approved 37 new drugs, either as new molecular entities or as new therapeutic biological products. Thus, high product development and commercialization by pharmaceutical industries created a higher demand for extractable and leachable testing services.

Furthermore, patient safety is the top priority for medical devices and pharmaceutical industries and they are making significant efforts to safeguard the final product. Pharmaceutical companies are investing largely to develop robust methods for leachable and extractable testing. According to Merck KGaA, leachable and extractable are compounds that can migrate from the container to the formulation and can produce serious adverse effects such as toxicity and adverse drug reactions. To mitigate this, the company developed its pre-qualified secondary Certified Reference Materials (CRMs) and ready-to-use CRM mixtures. This reference material is certified ISO 17025 and 17034. This guidance material from the company can act as SOP for analytical laboratories providing extractable & leachable testing services. Thereby increasing the demand for extractable and leachable testing services over the forecast period.

Moreover, the presence of regulatory authorities, such as the FDA and the U.S. Pharmacopeia (USP), is pushing manufacturers to test their products for E&L substances. In addition, the rising use of single-use technologies for scaling up the process and various strategic initiatives undertaken by market players will likely create lucrative growth opportunities for the market. For instance, in May 2022, Pacific BioLabs launched In Vitro Services to support the biopharma, pharmaceuticals, and medical device industries. This service aided in the expansion of the company's testing capabilities in analytical/bioanalytical and in vivo departments. Hence, the above-mentioned factors support the country's market.

Global Extractable And Leachable Testing Services Market Report Segmentation

This report forecasts revenue growth and provides an analysis of the latest trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the global extractable and leachable testing services market based on product type, application, and region:

Product Type Outlook (Revenue, USD Million, 2021 - 2033)

Container Closure Systems

Single-use Systems

Drug Delivery Systems

Others

Application Outlook (Revenue, USD Million, 2021 - 2033)

Parenteral Drug Products

Orally Inhaled and Nasal Drug Products (OINDP)

Ophthalmic

Regional Outlook (Revenue, USD Million, 2021 - 2033)

North America

U.S.

Canada

Mexico

Europe

UK

Germany

France

Italy

Spain

Denmark

Sweden

Norway

Asia Pacific

Japan

China

India

Australia

South Korea

Thailand

Latin America

Brazil

Argentina

MEA

South Africa

Saudi Arabia

UAE

Kuwait

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