

# **Global Pharmaceutical Sterility Testing Market Size study, by Product (Kits & Reagents, Services, Instruments), by Test (Membrane Filtration, Direct Inoculation, Rapid Microbial Method, Other Tests), by Type (In-house Testing, Outsourced Testing), by Sample (Sterile Drugs, Biologics and Therapeutics), by End-user (Pharmaceutical & Biotechnology Companies, CROs and Contract Testing Laboratories, Compounding Pharmacies, Other End-users) and Regional Forecasts 2022-2032**

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## **Abstracts**

The Global Pharmaceutical Sterility Testing Market was valued at USD 741.3 million in 2023 and is projected to grow at a compound annual growth rate (CAGR) of 10.8% from 2024 to 2032, reaching USD 61.1 Billion by 2032. Sterility testing is a crucial quality control procedure that ensures pharmaceutical products, including drugs and medical devices, are free from viable microorganisms. It involves testing samples for microbial contamination using methods such as membrane filtration or direct inoculation. Sterility testing is essential for verifying the safety and efficacy of injectable drugs, biologics, and aseptically produced products. By preventing infections and ensuring regulatory compliance, sterility testing maintains product quality and patient safety.

The market growth is driven by stringent regulatory requirements enforced by agencies like the FDA and EMA, compelling pharmaceutical companies to invest in comprehensive sterility testing procedures. Additionally, the rising investment in pharmaceutical R&D, particularly in biologics and advanced therapies, has increased the need for rigorous sterility testing. The expanding biopharmaceutical sector, with a

focus on biologics, vaccines, and gene therapies, further boosts the demand for specialized sterility testing. These products are highly susceptible to contamination, making sterility testing critical to their safety and efficacy. Also, advancements in sterility testing technologies, such as automated testing systems and real-time monitoring, present significant opportunities by enhancing testing efficiency, accuracy, and speed. Emerging markets, particularly in Asia-Pacific and Latin America, offer new growth opportunities as these regions increase their pharmaceutical manufacturing capabilities and regulatory standards. However, the high costs and complexity associated with advanced sterility testing technologies and maintaining compliance with evolving regulatory standards pose significant challenges. Small and mid-sized pharmaceutical companies may struggle with the financial and logistical burden, potentially hindering market growth.

North America dominated the market with a revenue share of 49% in 2023, driven by the increasing number of pharmaceutical industries and major market players in the U.S. and Canada. The region's market growth is attributed to the presence of technologically advanced CROs & CDMOs, increased allocation of grants, heightened drug development endeavors, and strategic measures such as innovation & acquisitions. Asia Pacific is expected to grow at the fastest CAGR over the forecast period, driven by investments from developed countries, regulatory amendments to facilitate local manufacturing & contract services, and rising healthcare demand due to population growth.

Major market players included in this report are:

Pacific Biolabs

Steris Plc

Boston Analytical

Sotera Health Company (Nelson Labs)

Sartorius Ag

Solvias Ag

SGS SA

Labcorp

Pace Analytical

Charles River Laboratories

The detailed segments and sub-segment of the market are explained below:

By Product:

- Kits & Reagents
- Services
- Instruments

By Test:

- Membrane Filtration

- Direct Inoculation
- Rapid Microbial Method
- Other Tests

By Type:

- In-house Testing
- Outsourced Testing

By Sample:

- Sterile Drugs
- Biologics and Therapeutics

By End-user:

- Pharmaceutical & Biotechnology Companies
- CROs and Contract Testing Laboratories
- Compounding Pharmacies
- Other End-users

By Region:

- North America
- U.S.
- Canada
- Europe
- UK
- Germany
- France
- Spain
- Italy
- ROE
- Asia Pacific
- China
- India
- Japan
- Australia
- South Korea
- RoAPAC
- Latin America
- Brazil
- Mexico
- RoLA
- Middle East & Africa
- Saudi Arabia
- South Africa

- RoMEA

Years considered for the study are as follows:

- Historical year – 2022
- Base year – 2023
- Forecast period – 2024 to 2032

Key Takeaways:

- Market Estimates & Forecast for 10 years from 2022 to 2032.
- Annualized revenues and regional level analysis for each market segment.
- Detailed analysis of geographical landscape with Country level analysis of major regions.
- Competitive landscape with information on major players in the market.
- Analysis of key business strategies and recommendations on future market approach.
- Analysis of competitive structure of the market.
- Demand side and supply side analysis of the market

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