

Pyrogen Testing Market By Product and Service (Reagents and Kits, Instruments, Services) , By Test Type (LAL Tests, Rabbit Pyrogen Test, Others) By End User (Pharmaceutical Companies & Biotechnology,, and, Medical Device Companies, Others) : Global Opportunity Analysis and Industry Forecast, 2024 - 2033

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Abstracts

The pyrogen testing market was valued at \$1.5 billion in 2022 and is projected to reach \$3.3 billion by 2032, registering a CAGR of 8.2% from 2023 to 2032. Pyrogen testing is a set of procedures and assays designed to detect the presence of pyrogens in pharmaceuticals, medical devices, and other healthcare products. Pyrogens are substances that induce fever when introduced into the human body, and they are often associated with the presence of bacterial endotoxins. In the pharmaceutical and healthcare industries, controlling and testing pyrogens is crucial as they cause adverse reactions in patients, such as fever and other immune responses.

Pyrogen testing involves in vitro methods using substances derived from bacterial sources, such as the Limulus amoebocyte lysate (LAL) test, which is commonly employed for endotoxin detection. Other methods include the monocyte activation test (MAT) and rabbit pyrogen test, although these are less commonly used due to ethical concerns and the availability of more sensitive and specific alternatives. The goal of pyrogen testing is to ensure the safety and quality of medical products by preventing exposure to pyrogenic contaminants that could compromise patient health.

Key factors that drive the growth of the pyrogen testing market include a rise in emphasis on ensuring the safety and quality of pharmaceutical and medical devices,

surge in the prevalence of chronic diseases, such as heart disease, diabetes, arthritis, cancer, & diabetes, and rise in demand for pharmaceuticals & medical devices. The development of advanced formulations in the pharmaceutical and biotechnology industries is a significant driver for the pyrogen testing market expansion. The increase in complexity of pharmaceutical products has necessitated the implementation of more quality control measures, leading to the adoption of pyrogen testing. In addition, the rise in number of pharmaceutical & biotechnology industries introducing complex formulations and cutting-edge medical technologies have led to the need for advanced and sensitive pyrogen testing methodologies, which propel the market growth.

Furthermore, growing initiatives for minimizing pyrogen contamination have led to global regulatory bodies and healthcare organizations to set strict standards. This mandates the adoption of strong pyrogen testing methods, contributing to the growth of the pyrogen testing market. For instance, regulatory authorities, such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and others, have established clear guidelines and standards for pyrogen testing. These guidelines outline the regulatory expectations and requirements for pharmaceutical and medical device manufacturers to conduct thorough pyrogen testing as part of their quality control processes. Thus, stringent adherence to these guidelines contributes significantly to market growth.

Moreover, the rise in technological advancements in pyrogen testing further boosts market growth. The development of innovative pyrogen detection methods, such as in vitro and in vivo testing, endotoxin testing, and recombinant factor C assays, enhances the accuracy and efficiency of pyrogen testing processes. For instance, Lonza Group company manufacture PyroTec PRO, an automated endotoxin testing platform that incorporates advanced technology to enhance the efficiency and accuracy of pyrogen testing. The system utilizes the well-established Limulus Amoebocyte Lysate (LAL) test method automates and streamlines the testing process. These technological advancements enable pharmaceutical manufacturers to adopt more reliable and rapid testing procedures, thereby propelling the market growth.

However, limited standardization for pyrogen testing hinders market growth. In addition, lack of knowledge and education about pyrogen contamination risks and testing methodologies hinder the widespread adoption of pyrogen testing in emerging regions. In contrast, expanding the medical device industry, with a focus on innovation and product development, and high growth potential in emerging countries are expected to provide lucrative opportunities during the forecast period.

The pyrogen testing market is segmented on the basis of product & service, test type, end user, and region. By product & service, the market is classified into reagents & kits, instruments, and services. By test type, the market is divided into LAL tests, rabbit pyrogen test, and others. By end user, it is segregated into pharmaceutical & biotechnology companies, medical device companies, and others. Region-wise, the market is analyzed across North America (the U.S., Canada, and Mexico), Europe (Germany, France, the UK, Italy, Spain, and rest of Europe), Asia-Pacific (Japan, China, Australia, India, South Korea, and rest of Asia-Pacific), LA (Brazil, Colombia, Argentina, and rest of LA), and MEA (GCC, South Africa, North Africa, and rest of MEA).

Major key players that operate in the pyrogen testing market are Merck KGaA, Lonza Group, Thermo Fisher Scientific Inc., FUJIFILM Holdings Corporation, GenScript, SEIKAGAKU CORPORATION, Charles River Laboratories, STERIS, WuXi AppTec, and Eurofins Scientific. Key players have adopted product launch as a key developmental strategy to improve the product portfolio of the pyrogen testing market. For instance, in August 2023, Lonza Group launched the Nebula Absorbance Reader, a new absorbance microplate reader which joins the company's portfolio of optimized instruments for streamlined endotoxin and pyrogen testing.

Key Benefits For Stakeholders

This report provides a quantitative analysis of the market segments, current trends, estimations, and dynamics of the pyrogen testing market analysis from 2022 to 2032 to identify the prevailing pyrogen testing market opportunities.

The market research is offered along with information related to key drivers, restraints, and opportunities.

Porter's five forces analysis highlights the potency of buyers and suppliers to enable stakeholders make profit-oriented business decisions and strengthen their supplier-buyer network.

In-depth analysis of the pyrogen testing market segmentation assists to determine the prevailing market opportunities.

Major countries in each region are mapped according to their revenue contribution to the global market.

Market player positioning facilitates benchmarking and provides a clear

understanding of the present position of the market players.

The report includes the analysis of the regional as well as global pyrogen testing market trends, key players, market segments, application areas, and market growth strategies.

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Additional country or region analysis- market size and forecast

Expanded list for Company Profiles

Historic market data

Key player details (including location, contact details, supplier/vendor network etc. in excel format)

Key Market Segments By Product And Service Reagents and Kits

Instruments

Services

By Test Type LAL Tests

Rabbit Pyrogen Test

Others

By End User Pharmaceutical Companies Biotechnology,, and

Medical Device Companies

Others

By Region

North America U.S.

Canada

Mexico

Europe Germany

France

UK

Italy

Spain

Rest of Europe

Asia-Pacific Japan

China

Australia

India

South Korea

Rest of Asia-Pacific

LAMEA Brazil

Saudi Arabia

South Africa

Rest of LAMEA

Key Market Players

Merck KGaA

Lonza Group AG

Thermo Fisher Scientific Inc.

FUJIFILM Corporation

Genscript Technology Corporation

SEIKAGAKU CORPORATION

Charles River Laboratories

Steris Corporation

Wuxi AppTec

Eurofins Scientific SE

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