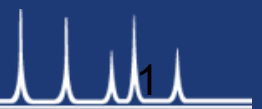




# PFAS

## 2025

### PFAS in Pharmaceuticals



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### INTRODUCTION

Per- and polyfluoroalkyl substances (PFAS) are a group of human-made chemicals widely used in various industries, including pharmaceuticals. In the pharmaceutical sector, PFAS can be found in certain drug formulations, primarily as surfactants to enhance solubility and bioavailability. However, their presence has raised significant health and environmental concerns, prompting regulatory actions worldwide.

### Health Implications:

Exposure to PFAS has been linked to several adverse health effects:

Thyroid Dysfunction: PFAS exposure has been associated with altered thyroid hormone levels, which are crucial for metabolic regulation. ([CDC - PFAS Health Effects](#))

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- Cholesterol Levels: Studies suggest a relationship between PFAS exposure and increased cholesterol levels, potentially elevating the risk of cardiovascular diseases. ([EPA - PFAS Health Effects](#))
- Immune System Effects: PFAS have been shown to affect the immune system, potentially reducing vaccine efficacy and increasing susceptibility to infections. ([EPA - PFAS and Immunotoxicity](#))
- Developmental and Reproductive Effects: Exposure during pregnancy has been linked to adverse outcomes such as low birth weight and developmental delays. ([ATSDR - PFAS Toxicity](#))

## **Regulatory Actions:**

Given the potential risks, regulatory agencies in the United States are scrutinizing PFAS usage:

- Environmental Protection Agency (EPA): In April 2024, the EPA finalized a rule designating two widely used PFAS—perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS)—as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly known as Superfund. This designation enhances transparency and accountability in addressing PFAS contamination. ([EPA - PFAS Hazardous Substances Rule](#))

- **Drinking Water Standards:** The EPA has established legally enforceable levels, known as Maximum Contaminant Levels (MCLs), for six PFAS compounds in drinking water, aiming to reduce exposure and protect public health. (EPA - Drinking Water Standards)

#### European Union Regulations:

- **REACH Regulation:** The EU's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation currently does not comprehensively cover many PFAS, leading to concerns about their widespread use. In 2019, the European Council called for an action plan to eliminate all non-essential uses of PFAS. A proposal to restrict the production, use, sale, and import of PFAS across the EU was submitted in January 2023. This proposal does not assess the use of PFAS in medicines, plant protection products, and biocides, as specific regulations apply to these substances. ([EFSA - PFAS Risk Assessment](#)).
- **Impact on Pharmaceuticals:** The European Federation of Pharmaceutical Industries and Associations (EFPIA) has expressed concerns that a broad PFAS restriction could lead to medicine shortages. They warn that a total ban could halt pharmaceutical manufacturing in the EU within three years, affecting the availability of over 600 essential medicines. ([European Pharmaceutical Review](#))

## Health and Environmental Concerns:

PFAS are associated with various health issues, including cancer, hormone disruption, and immune system effects. Their persistence in the environment leads to widespread contamination, further exacerbating public health concerns. Recent studies have highlighted the potential costs of PFAS pollution, estimating that cleaning up contamination could exceed £1.6 trillion in the UK and Europe over the next two decades. ([The Guardian - PFAS Pollution](#))

### Pharmaceutical Industry Considerations:

- **Regulatory Compliance:** Pharmaceutical companies must stay informed about evolving PFAS regulations to ensure compliance and avoid potential disruptions in manufacturing and distribution.
- **Supply Chain Transparency:** Engaging with suppliers to identify and eliminate PFAS-containing materials is crucial to mitigate regulatory and reputational risks.
- **Risk Assessment:** Conducting thorough assessments of the potential health and environmental impacts of PFAS in pharmaceutical products is essential to align with global sustainability goals and protect public health.

# **ADPEN Laboratories and PFAS Testing in Pharmaceuticals:**

ADPEN Laboratories provides Good Manufacturing Practice (GMP) testing services for PFAS in pharmaceuticals, ensuring that products are thoroughly tested for compliance with relevant safety and quality standards. As PFAS regulation in pharmaceuticals continues to evolve, ADPEN Laboratories is well-positioned to support pharmaceutical companies by offering specialized testing to detect and quantify PFAS in drug substances and products.

Key Services Provided by ADPEN Laboratories for PFAS Testing:

- **Testing for PFAS in Pharmaceuticals:** ADPEN Laboratories conducts precise and sensitive tests for PFAS, helping pharmaceutical companies meet stringent regulatory standards, such as those set by the FDA and other global agencies.
- **Accurate Detection:** ADPEN uses cutting-edge testing methods, using LC-MS/MS to accurately detect trace amounts of PFAS in pharmaceutical products, raw materials, and manufacturing processes.
- **Compliance with Regulatory Standards:** ADPEN Laboratories' testing services align with regulatory requirements for Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP). This ensures that pharmaceutical products are free from harmful levels of PFAS, which are critical to maintaining patient safety and product integrity.
- **Support for Global Regulations:** ADPEN's services also help clients comply with global regulations and guidelines, including those from the FDA, EMA, Health Canada, and EPA, to address concerns about PFAS contamination and meet safety thresholds.

In summary, while PFAS have functional applications in pharmaceuticals, their potential health risks necessitate careful consideration and proactive measures to mitigate exposure. ADPEN Laboratories provides the expertise and testing services needed to ensure that pharmaceutical products comply with the most stringent global standards for safety and quality.

ADPEN Laboratories is the standard for quality and excellence and our knowledge and experience in GMP and pharmaceutical testing enable us to provide assistance to the ongoing operations of pharmaceutical manufacturing companies. ADPEN performs analytical testing in our GMP and ISO/IEC 17025:2017 PJLA-accredited lab in Florida.



**LET ADPEN TAKE CARE OF YOUR TESTING NEEDS  
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