

# DRIVING INNOVATION AND SAFETY: THE CRITICAL ROLE OF EUROPEAN PHARMACEUTICAL EXCIPIENTS



## What are pharmaceutical excipients?


EU-manufactured excipients are essential to the safety, performance and scalability of modern medical products. Strengthening the EU's excipients industry is critical to sustaining pharmaceutical innovation, supply security and global competitiveness. They:



Ensure **stability and integrity of APIs** throughout shelf life



Control **delivery and release** to achieve the desired therapeutic effect



Enhance **bioavailability of complex and poorly soluble molecules**



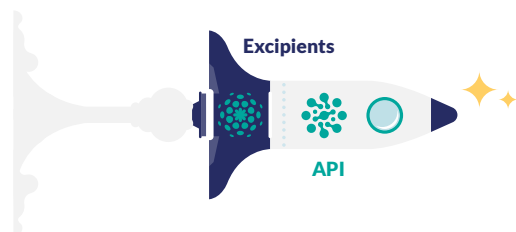
Improve **patient usability and adherence**



Enable **robust, cost-effective and scalable manufacturing**



Alongside APIs, pharmaceutical excipients are essential to medicinal products manufacturing—supporting innovation, supply resilience, and Europe's strategic autonomy while ensuring medicines are stable, effective, and safe for patients.



In every medicinal product, the API is the payload, delivering the therapeutic effect that treats, prevents or manages disease. Excipients are the propulsion system, enabling medicines to reach their destination safely and effectively.

## Pharmaceutical excipients at a glance



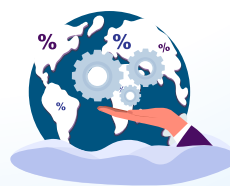
**95%**

Up to 95% of a medicine's mass is excipients



**€10Bn<sup>1</sup>**

Global market size



**38%**

With around 38% of global market share, Europe is the largest regional market for pharmaceutical excipients<sup>2</sup>



**Diverse origins**

synthetic, bio-based and mineral

<sup>1</sup> External Market Report - Pharmaceutical Process Materials Global Market Size and Dynamics - 2024 - Oliver Wyman

<sup>2</sup> Pharma Excipients Market to Project USD 16.12 Bn by 2035

# Excipients power innovation in modern medicines



Enable  
delivery of complex APIs



Unlock  
advanced drug delivery  
systems



Offer  
patient-friendly solutions



Innovative excipients enable more patient-friendly options, improving access and adherence. Example: they can allow biologics to be taken orally instead of by injection, maintaining the same therapy with greater convenience for patients.

## EU-manufactured excipients

A global benchmark for sustainability, quality and supply security



Rigorous EU regulatory and quality standards, including broadly applied voluntary schemes<sup>3</sup>

Leadership in bio-based and sustainable materials

Structurally lower carbon footprint

Fully transparent and traceable supply chains

Strong social and governance standards

<sup>3</sup> Excipients are subject to the scrutiny of multisector EU regulatory bodies. Given the diverse origin of excipients, IPEC & EXCI Pact define guides and standards to define the appropriate GMP, GDP & Quality Standards, with high uptake of EXCI Pact Certifications among European pharmaceutical excipients manufacturers.

## The EU pharmaceutical excipients industry

With a global market size of approximately €10 billion annually, excipients underpin the development, manufacturing and supply of modern medicines.

As the second largest excipients market globally, Europe plays a central role in:



Ensuring secure and reliable supply chains



Supporting innovation in advanced therapies and complex formulations

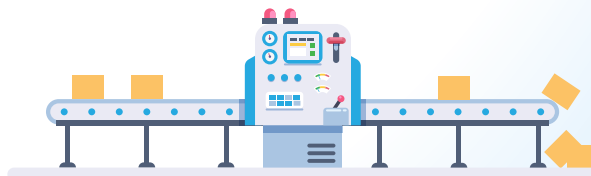


Maintaining high quality and regulatory standards

However, this position is not guaranteed.

Increasing global competition, cost pressures and shifting supply chains risk eroding Europe's leadership.

Sustained investment and policy support are essential to:



Ensure long-term patient access to safe and effective medicines

Safeguard Europe's strategic autonomy in medicines

Maintain a competitive and innovative industrial base

