THE VALUE OF PHARMACEUTICAL EXCIPIENTS

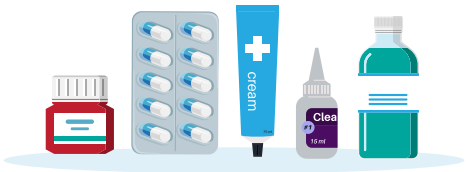
A European perspective

What is an Excipient?

"Any constituent of a medicinal product other than the active substance and the packaging material."

(Article 1(1)(a)3b DIRECTIVE 2011/62/EU on falsified medicinal products)

What About Excipients?

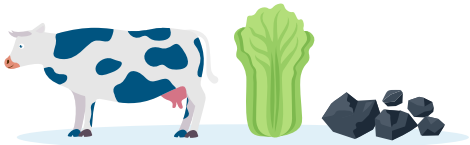


1,200+

There are more than **1,200 excipients** used in medicines.

Many factors

Factors used depend on many factors including the **drug type, route of administration and dosage form.**



Many origins

Excipients are diverse materials from many origins, **animal, vegetable or mineral.**

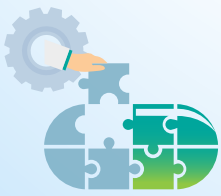
Many uses

Excipients are not exclusive to medicines, but are **used widely in food and cosmetic industries.**

Quality

Whatever their origin, however they are developed, made and handled, excipients must not compromise quality or harm patients.

What Can Excipients Do?



Act

as **filler/diluent** for highly potent medicines.

Enhance

solubility for poorly soluble medicines.

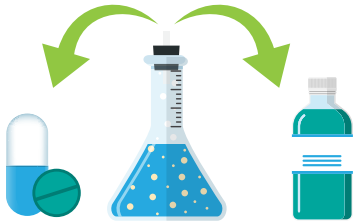
Control

the rate of drug release and bioavailability.

Innovation & Development

Excipients can boost research and innovation into medicines and:

Increase access to new drugs (for poorly soluble, unstable drugs).



Provide alternative routes of delivery and dosage forms (easier to use, taste better).

Improve patient compliance (reduce frequency of dosing, extend duration of action).

How Are They Manufactured?

Excipients are mostly produced on a large scale **using traditional chemical or biosynthetic processes.**

Regulations

Excipient manufacturers **are not covered by EU law directly**. **Manufacturers** of medicines **must ensure excipients and their suppliers are controlled**.

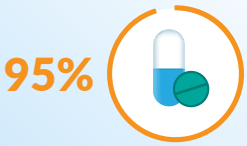
Key EU excipients regulatory references: 2011/62/EU Falsified Medicines Directive, European Commission Guidelines on Risk Assessment EC2015/C95/02 and Eudralex Vol 4, Part 1, Chapter 5 Starting Materials.

GMP & Quality Standards

Medicines must be safe, effective and of high quality. All **ingredients should be made according to Good Manufacturing Practices (GMP).**

Excipients manufacturers may apply standards from sectors including food and cosmetics. For medicines, voluntary guidance in the **IPEC-PQG GMP Guide is an important reference.**

Excipients Matter!



They can represent the biggest part of the medicine (up to 95%).

The patient can consume more excipient than active ingredient.

They have an important influence on drug safety.

efcg EUROPEAN FINE CHEMICALS GROUP

iPEC EUROPE 3 YRS

efcg.cefic.org
ipec-europe.org