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?

1200

There are more than 1,200 excipients used in medicines

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

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

Many are not exclusive to medicines, but are used widely in food and cosmetic industries

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)

It can take 10-15 years for such a new drug formulation to move from the laboratory to the market.

How are they manufactured?

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

Regulations

Excipient manufacturers in general are not covered by EU law directly. The manufacturer of the medicinal product must ensure excipients and their suppliers are controlled appropriately.


GMP & Quality Standards

Medicines must be safe, effective and of high quality. So all ingredients including excipients should be made according to Good Manufacturing Practices (GMP).

Excipient manufacturers may apply standards from a wide range of markets including food and cosmetics. For medicines, the voluntary guidance in the IPEC/PQG GMP Guide is an important reference.

Excipients matter!

- They can represent the biggest part of the medicines (up to 95%)
- The patient can consume more excipient than active ingredient
- They have an important influence on drug safety

IT IS ESSENTIAL THAT EXCIPIENT MANUFACTURERS, DISTRIBUTORS AND EXCIPIENT USERS COMPLY WITH ALL EXCIPIENTS STANDARDS AND REGULATIONS TO PROTECT PATIENTS.

THAT'S THE VALUE EXCIPIENTS BRING TO MEDICINES AND PATIENTS!