

# Your gateway to Europe for batch release

Are you planning to market a pharmaceutical product in the EU that's manufactured elsewhere? EU regulations require it to be tested in a cGMP-accredited lab within the EU to ensure quality and safety.





### EU batch release testing

We offer a wide range of testing services to support your product launch in the EU. Our state-of-the-art laboratory, equipped with advanced technology, and staffed by experienced professionals dedicated to maintaining the highest standards of quality and compliance.

We understand the importance of timely and accurate results, and our team is committed to providing reliable and efficient testing services to support your product launch in the EU.

### What does batch release testing include?

The scope depends on the product type but typically involves:

- Identity testing
- Potency/assay testing
- Purity and impurities
- Microbiological testing (e.g., sterility or microbial limits)
- Physicochemical tests (e.g., appearance, pH, disintegration)
- Container closure integrity
- Stability (ongoing and accelerated)
- Uniformity of dosage units

### Strategic partner

Normec Synergy Health is your strategic partner for EU batch release testing. Conveniently located in the Netherlands, our facility is just 50 kilometres from major European gateways, such as Amsterdam Schiphol Airport and the Port of Rotterdam. We have quick access to key transportation hubs, facilitating the smooth transfer of your products according to GDP standards.

Get in touch today to learn how we can support your product launch in the EU.