

Reverse Engineering



Reverse engineering (or deformulation) of pharmaceutical products aims to understand how a formulation works, what it is composed of, and which key parameters determine performance.

Our experience in reverse engineering, drug product characterisation, and formulation development enables us not only to quantify the components in a product, but also to assess formulation in detail and propose potential optimisation strategies.

What is reverse engineering?

Reverse engineering is used to understand the composition and critical formulation parameters of a product. The output can range from qualitative and quantitative composition analysis (Q1/Q2) to physical characterization and performance assessment.



Why reverse engineering?

- **Biowaiver / Bioequivalence (BE) strategy:** Helps demonstrate Q1/Q2 equivalence and, where needed, physical equivalence to ensure the developed product matches the reference product.
- **Formulation optimisation:** Improves product performance, stability, and manufacturability by better understanding excipient roles and interactions.
- **Comparative formulation analysis:** Compare reference products to support development decisions and benchmarking.
- **Patent and IP assessment:** Identifies potential patent risks and supports informed intellectual property decisions.
- **Regulatory alignment:** Highlights differences in excipient composition versus regulatory expectations and supports compliance strategies.

Typical deliverables

- Excipient identification (qualitative)
- Excipient quantification (Q1/Q2)
- Formulation characterisation summary, including key excipients, their roles, and potential critical attributes
- Q3-supporting characterisation of physical or functional comparators.
- Performance linkage (optional), such as dissolution, disintegration, or solubility insights to support formulation understanding
- Recommendations for next development steps such as formulation options and key risk areas)

Our reverse engineering services go beyond quantification!

We provide context and interpretation to support decision-making in development and regulatory strategy.