GreyRigge Associates Ltd.

Formulation Development & Stability

1. Formulations meet Pharmaceutical & administration requirements

Biopharmaceutical formulation development begins by aligning the drug product with intended administration routes—oral, injectable, topical, IV, etc. Requirements include viscosity, pH & osmolality. Ideally simple formulations must support safe, efficient delivery while meeting regulatory expectations.

2. Safe & painless

Patient comfort & safety are core design goals. This includes minimising site pain during dosing, optimising pH & osmolality & using accepted excipients. If well-formulated, a product should enable painless administration, especially for injectable or sensitive applications, as well as keeping the product stable & efficacious.

3. Compounding

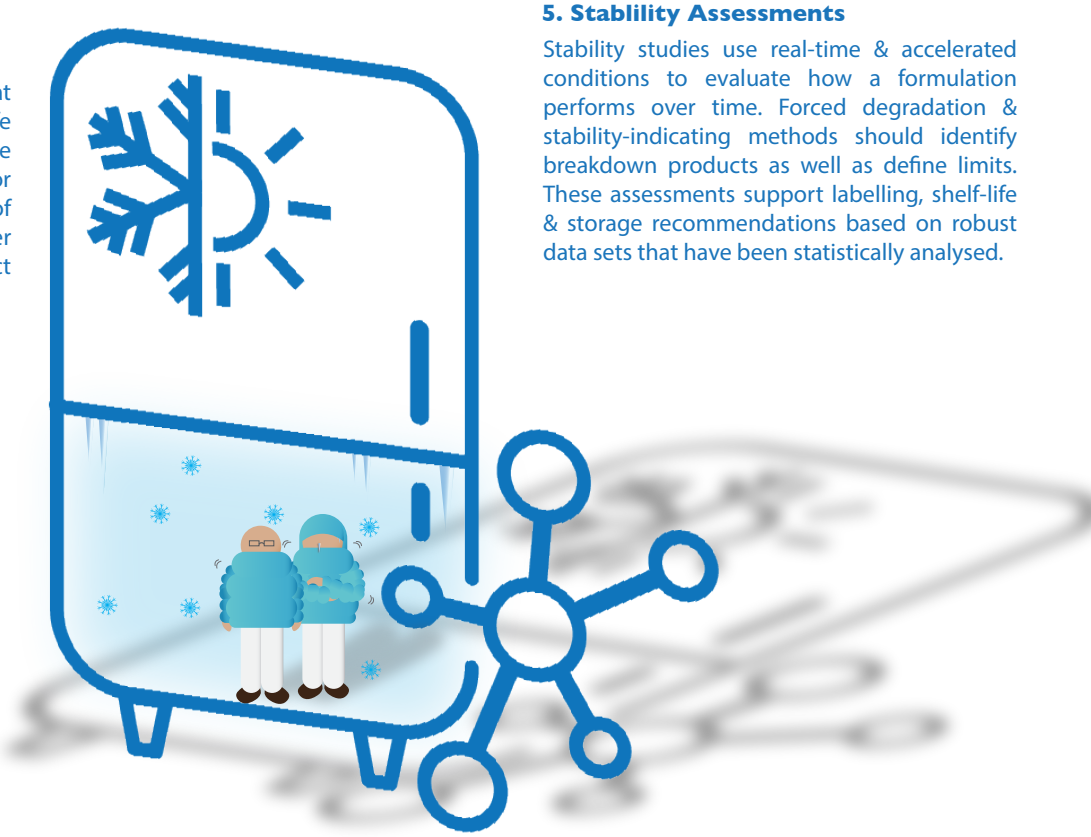
Compounding involves combining multiple components to create a final, usable dosage form. This process must be traceable, robust & performed under defined conditions. Each excipient used must be compatible and stable to ensure it contributes to a consistent & safe final drug product.

4. Drug Substance and Drug Product Shelf Life

Shelf life is established through testing that defines how long a substance remains safe and effective. This is important for both the drug substance & final product. Expiry or re-test dates are based on analysis of multiple stability studies performed under different storage conditions that relfect future use.

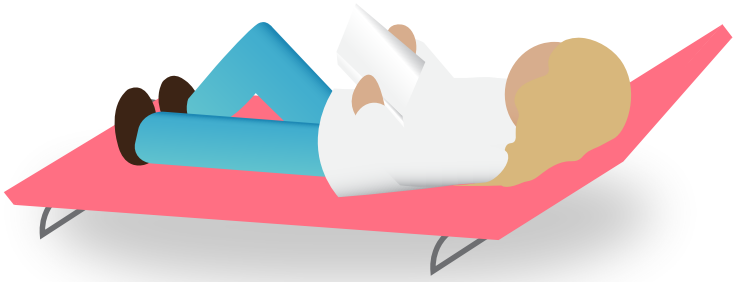
5. Stablility Assessments

Stability studies use real-time & accelerated conditions to evaluate how a formulation performs over time. Forced degradation & stability-indicating methods should identify breakdown products as well as define limits. These assessments support labelling, shelf-life & storage recommendations based on robust data sets that have been statistically analysed.



6. Product Storage Conditions

Storage conditions—temperature, light exposure, humidity—directly affect product quality and safety. Stability studies determine appropriate parameters & packaging requirements. Use of cold chains, such as fridges and freezers help control of environmental conditions to ensure that the product's integrity is maintained from manufacture through to final use in the patient.



Experts | Transformative | Agile

www.greyrigge.com