FORMULATION DEVELOPMENT #3 - CASE STUDY

ISSUE:
An intravenous dosage form of an orally active antibiotic. The physical properties and stability of the compound required a sterile blend with a buffering agent and sterile powder filing. The product was marketed in Europe and required extensive development of process and analytical methods to meet current ICH and FDA requirements. In addition, the drug substance process scale was increased and the final drug product presentation’s unit dose was increased to provide a more user friendly dosing by the medical professional.

OBJECTIVE:
To perform risk assessments to evaluate the impact of drug substance manufacture scaling, the increased unit of use dosage, the processing and define the design space for processing and ensure an optimized, robust and reproducible process the current strength process and develop a common granulation that could be used for all strengths that was safe, bioavailable and stable.

DELIVERABLE:
- To develop and optimize the drug product sterile powder filling process to meet current Quality by Design (QbD) principles and provided a product with improved stability, safety, and was bioavailable.
- Evaluation and optimization of a powder filling process using design of experiments that would provide a robust and reproducible process.
- Selection of appropriate primary packaging components.
- Development of product and ingredient specifications and re-development of methods based on scientific data, supported by method validation.
- Manufacture of Clinical Trial Supplies with appropriate documentation (batch records, batch release documentation).
- Stability studies to support shelf stability of drug products using 3rd party drug product manufacturers.

Contact Us
To learn more about how Verta Life Sciences can help you, please contact us:

Email: experts@Vertals.com  
Head Office: Verta Life Sciences, LLC  
            3737 Glenwood Ave, Suite 100  
            Raleigh, NC 27612 USA  
US Phone: +1 919-787-1921  
Free phone: +1 888-565-3179

Website: www.Vertalifesciences.com  
EU Office: Verta Life Sciences  
           Unit 1782, PO Box 92, Cardiff, CF11 1NB  
           UK

UK Phone: +44 (0)2921 25 0830