An orally active prodrug of a compound was developed for by a client. The formulation was developed for one dosage strength which required optimization of the process and modification to accommodate three additional strengths requiring a new formulation and process. The product had an accelerated approval status with the FDA which restricted development timelines.

To optimize the current strength process and develop a common granulation that could be used for all strengths that was safe, bioavailable and stable.

- To optimize the current strength and accelerate the CMC submission process for accelerated approval with fast follow on of a new formulation and common granulation process for all strengths that demonstrated safety, consistent bioavailability and stability based on Quality by Design (QbD) principles.
- Evaluation and optimization of a roller compaction process using design of experiments that would provide consistent bioavailability and stability for all strengths. Selection of appropriate primary packaging components.
- Development of product and ingredient specifications and 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 life stability of drug product using multiple drug substance suppliers and 3rd party secondary manufacturers.

Contact Us
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