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SOLID DOSE MANUFACTURING FOR CLINICAL TRIAL

Background

A major, generic pharmaceutical company developed a formulation for a drug product used to treat high cholesterol levels and to prevent cardiovascular disease. The company did not want to disrupt its own production capacity owing to the small volume of tablets required for the clinical trial studies; therefore, it contracted the production with Parsolex. After formulation development, the next step was to produce quality tablets onto which two different types of functional coats could be applied for use in a bioavailability and bioequivalence clinical studies.

Challenge

The moderate-dose drug product required the full spectrum of solid dose manufacturing processes, including high-shear granulation, granule drying and milling of the resultant granules. Blend homogeneity testing was required to ensure that the blending process would provide appropriate content uniformity. Stratified samples needed to be obtained periodically throughout the tableting process and tested to ensure that the content uniformity of the final dosage form content was consistent. Furthermore, the 10-mm round tablets needed to be divided and coated as either extended release or a combination of extended release and delayed release.

Solutions

Parsolex worked together with this generic manufacturer to create a detailed work plan and implemented the agreed-upon activities. Ultimately, the tablet cores were film coated either with the extended-release functional coat alone or with the extended-release functional coat followed by the delayed-release functional coat. In-process testing ensured consistent drug product (as demonstrated by final analytical testing) for use in the client-sponsored clinical trials. The resulting tablets were bottled and labeled, and samples were placed in accelerated, intermediate, and long-term stability studies. The partnership with Parsolex freed up the generic company's production capacity, which could be utilized for major production batches of lifesaving commercial products.

Let us know [how we can help](#) with your Solid Dose Manufacturing and Clinical Trial needs today.