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Profiller 1100/1120 Hand-Held Capsule Filling System for Use in Selection and Laboratory Development of Over-Encapsulated Products

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Over-Encapsulation (OE) & OE Study

Over-encapsulation (OE) is a widely used, cost-effective technique which involves the blinding of a solid dosage form into a capsule shell to eliminate bias from comparative clinical trials while maintaining study integrity and efficacy. It also allows for comparison against drug products and placebos, as well as removing potential patient bias of the placebo effect against the treatment effectiveness.

Small-scale development activities are important to determine optimal parameters prior to a full-scale manufacturing commitment. The Profiller 1100/1120 Hand-Held Capsule Filling System can aid in this development by quickly and consistently preparing small-scale quantities of OE products for development activities, especially for analytical method development.

However, there are many variables that can affect the complexity of the OE process. Important for consideration during the selection and development of OE products include capsule shell type and size, appropriate backfill selection, variables in commercial dosage comparators used, as well as any impact these variables may have to the analytical methodology itself.

Analytical testing is a critical step in support of clinical trials. The HPLC and dissolution data generated from this testing can be used to assess viability of the OE products. The stability data generated from analytical testing, which is required throughout the length of the study, is critical to support the continued clinical use of the product. Development activities and analytical testing can provide early insight into the chemical stability of commercial vs. OE Products utilizing multiple analytical techniques. Considerations for analytical testing may include appearance, assay, identification, dissolution, impurities, and water content. Each testing parameter provides critical information for ensuring a safe and effective product.

- Appearance, assay, and identification testing ensures the correct drug product was OE'd and that the potency in the OE product is stable and within specifications.
- Dissolution testing is important to monitor any delay in release of the active drug caused by the OE of the drug product, as well as to assess bioequivalence. Finding a suitable dissolution method for the drug product which avoids cross-linking and other issues caused by the capsule shells and/or backfill used for OE product is the primary goal of dissolution method development.
- Impurities testing is essential to monitor for any impurities in the OE drug product which arise due to the capsule shell and/or backfill. It's also used throughout a longer period to record the growth of the impurities present in the OE product compared to the commercial product. A suitable Impurities method needs to be developed which is applicable to the commercial product, OE product and placebo.
- Water content analysis is an essential testing element throughout the drug development lifecycle for quality control purposes. The level of moisture content can significantly influence the physical properties and quality of nearly all substances and materials at all stages of development and within the final product. High moisture content can also lead to faster degradation of drugs and as such needs to be carefully monitored and controlled.

Almac is a leader in over-encapsulation, analytical method development/validation and manufacture. Our Analytical Services team works on the development and phase appropriate validation of analytical methods to support release testing as well as stability studies for API, Drug Products and reference standard certification on behalf of external

clients. Our analytical expertise, coupled with equipment like the Profiller 1100/1120, allows us to perform pre-manufacturing method evaluation and provide superior solutions to take analytical method development off the critical path. Our early analytical screening services helps to identify possible manufacturing issues and provides opportunities to accelerate critical timelines. Almac Sciences' expertise and close collaboration with customers allows us to provide exceptional, high quality and transparent analytical services.

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