



Pharmaceutical Sciences

FACTSHEET



Precision Dosing Using the Xcelodose® 600S

Potential and Opportunity

The importance of accelerating the supply of material into the clinic is well documented. Capsugel's Xcelodose® system enables the robust, reproducible and precise filling of drug substance directly into capsules. By linking the Xcelodose® system to Aptuit's solid form screening and crystallization capabilities in West Lafayette, Indiana with API synthesis in Oxford, Scotland or Kansas City, U.S., it is possible to eliminate the need for many early development activities for Phase 1 studies yet still have a fully characterized API. Furthermore, Aptuit's crystal in a capsule strategy means you know what you have and can easily move to the next stage of development if your First-in-Man tests are positive. Aptuit's customers can access this technology within GMP facilities at Livingston, Scotland and Kansas City, Missouri

The Technologies

The Xcelodose® 600S automatic and programmable system fills precise quantities of drug substance from .1 mg to 250 mg into capsules. The tailor-made software records the weight of drug substance in each capsule. Up to 600 capsules (from size 00 through to 4) can be individually filled and weighed per hour. Typically with an RSD of <2%. Aptuit's fast solid form selection and crystallization strategies mean it is possible to prepare a well characterized controlled API for these First-in-Man studies without increasing the timeline. The co-crystals or amorphous dispersions can be evaluated for bioavailability in animal models at the Aptuit Preclinical Group located in Riccarton, Scotland. Having a well characterized material greatly facilitates IND filing and makes going to Phase II trials much easier and faster. API synthesis completed under the Aptuit umbrella of services can further expedite time to clinic through the seamless transfer of methods and release testing from API to finished product.

The Benefits

- Faster drug development.
- Less wastage of drug substance.
- Removes requirement for excipients and simplifies drug product stability.
- No formulation development for early studies.



- Highly consistent dose accuracy.
- Software automatically optimizes the filling process.
- Accelerates NCE kill rate and formulation development timescales.
- Also suitable for filling blends, granules and pellets.
- Can be used to supply capsules for use in inhaled devices.
- Software is 21 CFR Part 11 compliant.
- Multiple studies have been supported since March 2002 from the facility supporting oral and inhaled programs.

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

For information about Aptuit's services, please call or email:

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Engineering a better drug development process.