



AURIGENE

PHARMACEUTICAL SERVICES



Case Study

Expediting early development through innovative precision capsule filling technology



Introduction:

Any new chemical entity (NCE) needs to undergo various stages of development such as preclinical and clinical trials before drug product is approved by regulatory agencies and available for patient. Formulations developed during early phases are simple formulations to enable phase appropriate studies like screening, dose ranging, toxicological and double blinding studies. Aurigene offers simplified formulations with unique and innovative precision filling encapsulation technologies to cater to early clinical supplies with minimum drug substance in a short span of time. Short development time to reach the preclinical trials decision point, which allows an increase in throughput of candidate compounds for development.

Aurigene developed the product with multiple doses and deliver clinical supplies for phase-1 clinical trial for a double blinding study. This drug product is a cytotoxic molecule intended for treatment of cancer.

Challenges:

- Drug substance had very poor flow properties with batch to batch inconsistency in bulk density and particle size distribution
- Drug quantities available for development work was very minimal
- Look-a-like capsule formulations to be supplied for multiple doses from 5 mg – 80 mg
- Minimum scope for formulation development due to short delivery time lines for clinical supplies



Solution:

Formulation development involved few pre-formulation experiments with minimum API. Dose proportionate formulation was developed for multiple strengths and encapsulation was performed using high end precision filling encapsulation technology, Xcelodose® System.

1. Precise filling was ensured during filling for all doses with minimum weight variation resulting good content uniformity. The % Relative Standard Deviation (%RSD) was only 0.4 % and Acceptance Value (AV) was 1.0 (Limits being $AV \leq 15.0$).
2. Formulation expertise with deep scientific understanding blended with high end automatic capsule filling machine helped in delivering the clinical supplies within a short time lines. This enable us in saving at least 6 months of development cost and time for our customer.

Above data indicates that sophisticated equipment like Xcelodose® can assist in quick development and delivery of NCE molecules especially for preclinical studies. Xcelodose® system, an automated and programmable machine for precise metering of drug substance or granules into capsule. Aurigene offers below services for expedited early phase formulation development and preclinical supplies -

1. Formulation Development of potent and cytotoxic compounds with minimum amount of available API (50 to 100 g).
2. Stable formulation development with or without excipients.
3. Pre-mix development for poorly soluble drug.
4. Deliver drug product with precise low weight filling as 100 micrograms and up to 100 milligrams and beyond with look-a-like formulation strategy to enable double blinding studies.
5. Batch manufactured with record of individual capsule fill weight.

The above advantages in turn provide the opportunity for customers to potentially recoup investments made to develop new medicines and to fund future research.

Thank You



For more information please visit
<https://www.aurigeneservices.com/>



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