Case Study: SD Feasibilities

Background

A mid-sized, publicly traded U.S. Pharma specializing in kinase biology and developing treatments for cancer, inflammation and autoimmune conditions engaged with CritiTech to evaluate kinase inhibitors as candidates for formulation into dry powders using spray drying (SD).

The client had not used SD on the candidates and had no specifications developed. The initial project was to evaluate three candidate APIs by conducting solubility screening, SD feasibility, dissolution evaluation, secondary drying evaluation and short-term stability. As we completed initial feasibility studies on the first three candidates, the client continued to submit new candidates for feasibility assessment. Eventually, CritiTech was engaged on numerous feasibility, production and stability projects over the course of three years, becoming a formulation development partner for the client.

GOAL

Create flowable dry powder formulations for advancing kinase inhibitor API candidates from preclinical to clinical development

Challenges

- New chemical entities with unknown solubilities
- No existing spray drying parameters or target specifications
- Short deadlines for individual API assessments

Approach

- Leveraged early project learning to design experiments for future candidate APIs enabling a “fail fast” approach for API evaluation
- Applied experience with other NCEs to quickly identify essential SD parameters and target specifications - minimizing time spent in evaluating candidate APIs
- Committed dedicated staff and equipment to multi-run days to further expedite timelines

Results

- 13 candidate APIs evaluated over a 16-month period, each completed in as fast as 5 business days
- More than 145 SD manufacturing runs
- 8 GMP manufacturing runs for clinical trial material
- 5 stability studies completed from 1 week to 1 year
- 13 API candidates evaluated on time and on budget
- 1 API candidate progressed to GMP batches for clinical trials
- 1 API candidate currently in preclinical testing

Client Impact

- Benefited from significant time and cost savings due to our approach and expertise
- Averaged less than 2 weeks per feasibility study vs industry standard 4-6 weeks
- Progressed 2 candidates out of feasibility including one to GMP production with a single CDMO partner
- Developed relationship with CT PES team to perform as a trusted partner on early formulation, production and stability services

> **Your turn-around times are much faster than other CDMOs we have worked with.**
>
> **-Client Drug Product Development Leader**

Total SD Feasibility Projects Completed

January-March Yr 1		July-August Yr 1		April Yr 3	
3 APIs	6 Weeks	6 APIs	4 Weeks	4 APIs	2 Weeks

CritiTech
Particle Engineering Solutions

A full service, U.S.-based CDMO
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