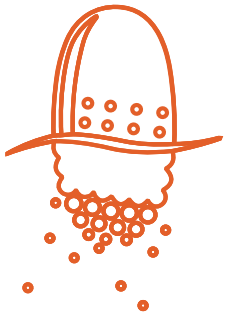
Renejix
Softgel Technologies

TECHNICAL NOTE

Small Batch Size Optimization as a Solution for Formulation Challenges



Executive Summary (Key Insights)

In drug development, a shortage of the Active Pharmaceutical Ingredient (API) during the initial stages can impede progress. However, Renejix has introduced a method that utilizes industrial machinery right from the start. This approach enables the efficient production of high-yield cGMP batches, eliminating the previously encountered delays in drug development.

The Challenge

In the current scenario, limited Active Pharmaceutical Ingredient (API) quantities pose significant challenges. When using lab-scale equipment for development, two main issues arise:

1. It necessitates a later, costly shift to larger manufacturing processes, prolonging timelines and requiring substantial resources.
2. It risks non-compliance with regulatory or clinical trial standards, as many lab-scale equipment fail to meet current Good Manufacturing Practice (cGMP) standards.

Alternatively, traditional methods for handling small API batches present challenges such as labor-intensive processes and reduced product yield.

The Renejix Solution

Renejix specializes in small batch manufacturing, leveraging innovative techniques to achieve remarkable outcomes, including:

1. Precise production adhering to cGMP standards.
2. Consistent yields ranging from 84%% to 97%.
3. Expedited development by establishing Quality Process Parameters early on.
4. Flexibility in accommodating various capsule shapes and sizes to meet industry demands.

Renejix's success is highlighted by a case study on our advanced tooling system. We rigorously tested three formulations and their effects on production yield. See Table 1, Column 1, Page 2 for results. Each batch, tailored to specific capsule sizes, was split into two fractions for thorough scrutiny and evaluation.

Renejix aimed for precision and consistency by initially configuring machine settings for a critical trial. They then fine-tuned these settings for each batch within a single campaign.

Throughout the manufacturing process, Renejix maintained strict in-process controls. Detailed quantification of product losses at each step (Table 2) indicated that machine setup presented the primary challenge, effectively addressed by Renejix.

These insights led to significant yield improvements (Table 1). With Renejix's advanced tooling and settings, yields consistently exceeded 80%, in contrast to the typical 20%-30% yields from conventional equipment. All in all, no specific trends were observed, underscoring the effectiveness of Renejix's approach.

Table 1: Mean Yield Achieved by Encapsulating 500g and 1000g Fill Mix Batches using Various Formulation Types and Softgel Capsule Sizes/Formats

Formulation Type	Capsule Format (Fill Weight)		
	2 oval (100mg)	7.5 oval (400mg)	20 Oblong (1000mg)
Medium chain triglycerides *(Hydrophobic)*	90.6%	96.6%	93.3%
Semi-solid lipophilic system *(Hydrophobic)*	93.9%	87.0%	84.0 %
Macrogol 400 *(Hydrophilic)*	88.4%	91.9%	94.4%

Table 2: Global Reconciliation - Identification and Quantification of Measurable Losses In One Batch

Step	Fraction					
	Medium chain triglycerides *(Hydrophobic)*		Semi-solid lipophilic system *(Hydrophobic)*		Macrogol 400 *(Hydrophilic)*	
	1 (%)	2 (%)	3 (%)	4 (%)	5 (%)	6 (%)
Transfer in hopper	1.1	0.4	0.0	0.0	1.4	1.8
Machine set-up	2.9	1.5	2.3	1.3	1.9	3.2
Encapsulation IPCs	0.4	0.2	0.2	0.2	0.3	0.3
Drying IPCs	0.1	0.1	0.1	0.1	0.1	0.1
Inspection step	0.4	0.0	0.0	0.0	0.0	0.1
Packaging step	0.0	0.0	0.0	0.0	0.0	0.0
Total Measurable Losses	4.9	2.2	2.6	1.6	3.7	5.5

Global Reconciliation Global Reconciliation (%) = [Quantity Of Packaged Capsules + Product Losses (Capsules)] / [Theoretical Batch Size (Quantity Of Capsules)] X 100

Conclusion

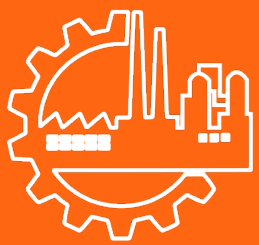
Renejix presents a novel approach to softgel drug molecule development. The process seamlessly operates on industrial-scale machinery, requiring just 500ml of fill material.

With meticulous attention to detail, Renegix has optimized process parameters, equipment, and tooling fabrication to deliver exceptional results. This underscores Renegix's commitment to cGMP quality standards and the effective enhancement of small batch production yields.

300+ Technology Transfers and products developed

Advanced Supply Chain & Network

3+ billion doses manufactured annually



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