AURIGENE
PHARMACEUTICAL SERVICES


# Case Study

## Systematic formulation design - shorten development cost & time

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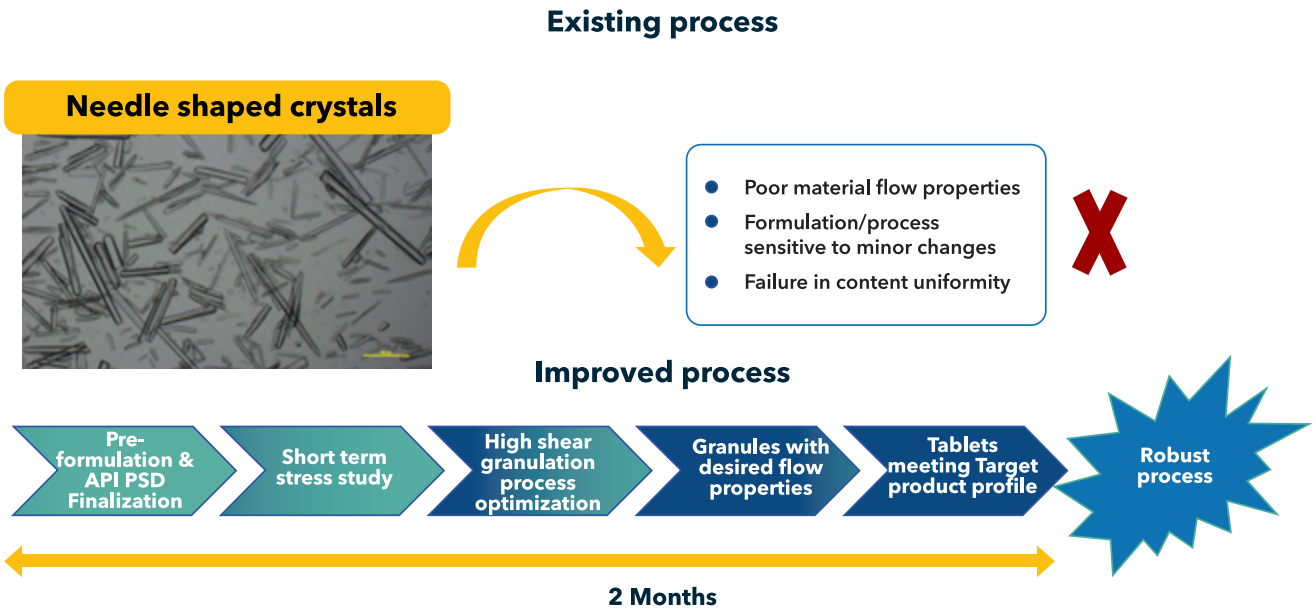
|---|---|
| **Customer:** | Medium sized pharmaceutical company |
| **Location:** | USA |
| **Indication:** | Treatment of severe plaque psoriasis |
| **Strength of product:** | 150 mg |
| **Dosage form:** | Tablet (Immediate release) |
| **Scope of work:** | Development and clinical supply for Phase II studies |

# Project Challenge:

- Existing formulation (lower strength - 50 mg) was manufactured using direct compression process. This formulation posed poor powder flow and content uniformity issues during scale-up.
- Development of new strength 150 mg without any process issues was a challenge.

# Solution design:

- Preliminary pre-formulation, stress study and PSD impact assessment enabled to understand the molecule nature
- API Process engineering team helped to achieve appropriate particle size in a short span of time which was used for development
- API being needle shaped posed problems when processed by DC process. Hence, new formulation of 150 mg was developed by wet granulation approach.
- Robust process was developed within 2 months period such that same composition could be applicable for conducting dose ranging study without need for further formula or process optimization
- The unique attribute of the developed formulation was that it could accommodate 50-200 mg of active ingredient without change in tablet weight. This enabled the customer to quickly fine-tune / finalize the dose based upon clinical study.
- Activities included, QbD based risk assessment, PSD finalization, Stress studies on API and formulation to understand the drug nature, formula and process design and optimization
- As the molecule is undergoing clinical trials, the developed formulation provides flexibility with respect to dose and advantage of cost/time which is otherwise needed for development of newer strengths ensuring continuous support for clinical trials




# Conclusion:

- Formulation development and optimization within 2 months with deep scientific understanding and systematic approach.
- DS-DP integration for on time delivery.
- Flexible formulation design to accommodate different levels of API with aim of reducing time and cost of development of newly added strengths.

# Thank You

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