

# Solution Engine: Solubility Enhancement

Develop ASD prototypes for Clin Dev with 50-100mg API



## In Silico Modeling

- Computer software
- Hansen and Florey-Huggins
- Active material chemical structure
- Polymer type/chemistry
- Screen >20 polymers-API combinations
- No API required
- Timeline: <1 day



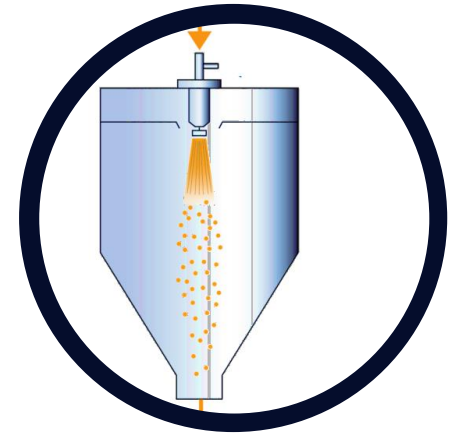
## Miniaturized Screening

- Minimize Number of experiments
- Based on In Silico Results
- 50 mg to 100 mg API required
- Up to 10 to 20 combinations screened at once
- ASD Dissolution ranking
- Timeline: < 2-3 weeks



## Animal PK (In vivo validation)

- Two rounds of Rodent PK study
- Final ASD formulation selection
- Animal PK provides more accurate product performance data compared with in-vitro dissolution studies only.
- Timeline: < 5 days/round



## Process Selection/Optimization

- Spray Drying vs Hot Melt Extrusion
- Assay/non-sink and sink Dissolution method development
- Small scale: 1 to 5 gm
- Scale up and clinical manufacturing
- >1 Kg to > 100 Kg

# Solution Engine: Controlled Release

Develop CR prototypes for Clin Dev with 1-5g API



## Modified Release

- Mini-tablets with functional coating
- Size 9 capsules
- Delayed release for targeted pH delivery
- Modified release for desired PK profile
- 1-5g API required
- Assay/Dissolution method development
- Timeline: < 8 to 10 weeks



## Animal PK (In vivo validation)

- Two rounds of Rodent PK study
- Final Controlled Release formulation selection
- Animal PK provides more accurate product performance data compared with in-vitro dissolution studies only.
- Timeline: < 5 days/round

## Process Selection/Optimization

- Tablet, Capsule, mini-tablet, drug layering, Extrusion Spheronization
- Pan Coating, Fluid-bed Coating
  - Small scale: 1 to 5 gm
- Scale up and clinical manufacturing
  - >1 Kg to > 100 Kg