

Case Study



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“Scale-up presents a significant challenge (both in time and money) in certain pharmaceutical processes. ANSYS helped us through multiple strategic consulting projects in generating necessary process understanding and accurate scale-up conditions for our mixing tanks to go from lab scale to plant scale. We received valuable insights into the physics of scale-up and the risks involved. These simulations helped us in decision-making on equipment sizing and cutting down on expensive raw material usage for the testing process.”

*RaviChandra Palaparthi
Head, Modeling and Simulation
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Scale up study for a complex generic drug product

The pharmaceuticals industry faces diverse challenges, ranging from drug delivery to design optimization of equipment to resolving scale-up problems. Dealing with increasing raw material costs and the unavailability of the right raw materials at the right time create major issues in meeting stringent product delivery deadlines. Hence we explored engineering simulations to help us address these challenges effectively.

Challenges

We engaged with ANSYS to take advantage of their expertise in this field so we could get quicker results and learn faster. ANSYS Consulting helped us to develop accurate scale-up conditions by performing steady-state and transient simulations at each scale, and studying parameters like velocity distributions, mixing times and species concentrations from one scale to the other.

Technology Used

ANSYS CFD, ANSYS SpaceClaim, ANSYS Mesh, ANSYS Fluent

Engineering Solution

ANSYS consultants used simulations to help us to understand:

- Differences in micro-, meso- and macro-mixing times from lab scale to plant scale
- Risks involved in the scale-up at each particular rpm level
- Dead zone formation in plant scale simulations
- The evolution of individual species concentration and mixing performance using transient simulations



Benefits

Consultation with ANSYS on engineering simulations helped us in following ways:

- Providing valuable insights into the physics of scale-up and identifying the risks involved
- Guiding in lowering the risk of scale-up batches
- Helping make better informed decisions where minimal experimental data existed or where experimental data was difficult to get. In one case, this translated into a 50 percent reduction in uncertainty in identifying the right process window even before we had the raw material for experimentation.
- Facilitating the buy-in for engineering based decision making from the non-engineers



Dr. Reddy's is a NYSE listed company which manufactures and markets APIs, Finished Dosages and Biologics in over 100 countries worldwide. Dr. Reddy's is a vertically integrated global pharmaceutical company with proven research capabilities, including a promising drug discovery pipeline and presence across the pharmaceutical value chain.

The company has expertise in scaling up complex products from lab to the plant scale with an array modeling tools. Process experts in the company help in reducing the scale-up risks from lab to the plant.

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