



Our Performance - Human Healthcare Product

MULTI-STEP HUMAN HEALTHCARE PRODUCT

Situation: Customer was looking to procure this 3-step API at commercial quantities and Resonance had to develop the process details as well. Timeline was 20 weeks

Week 1

- Formed a project team
- Conducted literature search for synthesis route
- Assigned quality as per USP, Ph.Eur, BP
- Conducted feasibility study to commence the work

Week 1-4

- Procured raw materials
- Completed 50 gms synthesis
- Tested sample in-house and cleared for purity requirement

Week 4-8

- Developed analytical method for in-process check
- Initiated 500 gms experiment
- Tested 500 gms sample and cleared for quality



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Week 8-12

- Completed 3 batches at 5 kg scale
- Optimized input ratios and output norms
- Developed analytical methods for residual solvents
- Approved samples from 5 kg experiment

Week 12-16

- Up-scaled optimized process to 10 kg
- Supplied 50 kg to the customer

Week 16..

- Incorporated impurity profile (<0.10% unknown) as new benchmark
- Modified process in lab at 500 gms scale to meet new quality standard
- Modified process was scaled up to 10 kg and further to 55 kg level
- Validated process
- Supplied commercial quantities of 100 kg lots to customer
- Conducted stability studies to establish shelf-life
- Registered product with EDQM and obtained COS
- Prepared DMF in CTD format

Resonance Delivered:

- Required quantity at spec within timeline
- Provided necessary documentation for regulatory requirements

