



AURIGENE

PHARMACEUTICAL SERVICES



Case Study

Mitigating technical challenges and cost impacts by improved process design





Project challenge:

Synthesis of a phase II NCE involved an intermediate that had high propensity to racemize. Also at isolation there was very low yield which contributed to product cost. Other major challenges included use of pyrophoric reagents, hydrogenation in specialized reactors and purification involved multiple column chromatographic steps.

Solution design:

Identification of critical process parameters and redesigning of the process with a commercial objective was achieved. Highlights of the approach:

- Racemization of chiral intermediate was prevented by reactant redesign whereby yield was improved three-fold which had significant impact on the overall RMC
- Exploiting difference in chemical reactivity of functional groups, safer alternative reagents were selected to replace pyrophoric reagents
- Replacement of corrosive additives resolved the use of specialized reactors for hydrogenation
- Efficient crystallization methods to bypass column chromatography and finally arrive at the desired polymorph

Racemization of chiral intermediate prevented by reactant redesign, tripling yield.

Conclusion:

This case study showcases the holistic approach adopted by our scientists in designing a commercially viable process and the cost impact of a technically strong product design.

Thank You



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Mail us at
contactapsl@aurigeneservices.com