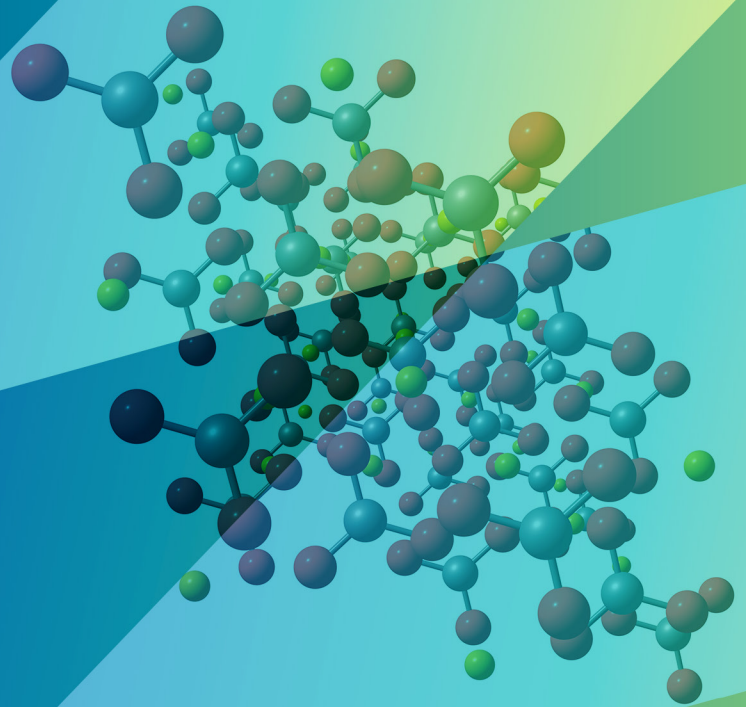




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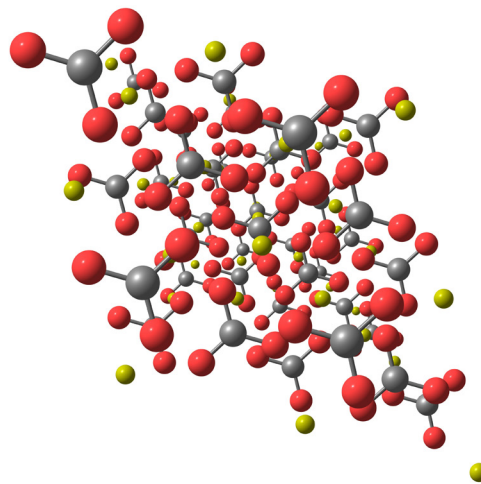


Case Study

Product development in
a challenging IP landscape

Project challenge:

Identification of suitable chiral reagent for chemical resolution, process validation, desired polymorph.



Solution design:

Often API development is bound by IP constraints. In order to develop a scalable and robust process to address IP challenges, the following approach was adopted by the CPS team.

- Non-infringing route to circumvent IP barrier was proposed
- Screening of chiral resolving agents and solvents to yield the maximum efficiency in terms of yield and highest desired enantiomer
- Polymorph screening with different solvent systems and a range of temperatures furnished the requisite
- Process developed in lab was demonstrated in plant by performing three process validation batches yielding the product with desired quality and culminating in regulatory filing

**Robust process to
address IP challenges**

Conclusion:

Our team has demonstrated the ability to develop processes for commercial API that are already in the market with restrictions in IP and enable the submission of a regulatory filing

Thank You



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Mail us at
contactapsl@aurigeneservices.com