



Case Study

Manufacturing an activated mPEG derivative

Background:

A big pharmaceutical company approached Aurigene Pharmaceutical Services for manufacturing an activated mPEG derivative. The process involved 11 stages. Three major chain stages and eight intermediate steps.

Challenges:

- Stage-1 and 2 reactions are sluggish and observed unreacted starting materials which is difficult to purify.
- Only 10-20% product formation observed in stage-3.
- Stage-3 product was unstable under reaction conditions and during isolation.
- The key intermediate is not commercially available and involves complex chemistry.



Aurigene solution:

- Optimized the mole equivalents of reagents in all stages to drive the reaction for completion, which helped to avoid carryover of impurities to final stage.
- Screened multiple bases/solvents/temperature for stage 3 and ensured the completion of reaction.
- Identified suitable isolation and storage conditions (-20°C) to avoid the stage-3 product degradation.
- Optimized the final stage reaction & purification process to achieve >90% purity.
- Appropriate optimization of the parameters helped in successful scale up of side chain (key intermediate).

Outcome:

- Successfully manufactured an activated mPEG derivative in several campaigns.

Thank You



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