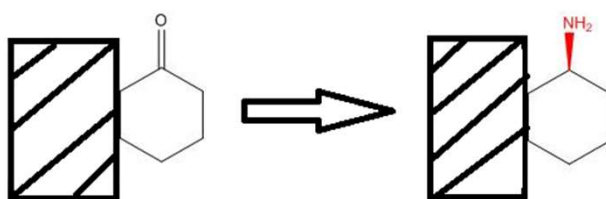


Case Study-1

Process Development of RSM of a Ph2 API:



Scope:

Process Development of RSM followed by 300 gm for Initial shipment.

Complexity:

RSM of a Phase-2 API, chiral chemistry and discrepancy in Purities between the batches. The current source was not helping to solve the problem.

Quality & Yield:

Purity inconsistency as the Sample must be stored under -20°C

Accomplishment:

It was identified that the purity was affected by process carryovers from the Chiral RSM. Our scientists quickly sourced a local vendor and conducted a few trial batches. A rapid stability test confirmed that the RSM could be stored at $2^{\circ}\text{-}8^{\circ}\text{C}$.

Shilpa delivered 300 gm ahead of timelines and become a continuous supplier for subsequent requirements.

