

Solve API Preparation Problems, Supply API, and Support GLP Toxicology for IND

SUMMARY

Assist client in solving API preparation problems, supply API, and support GLP toxicology for IND.

APPROACH

Client initiated a 28-day toxicity study in dogs, which was on critical path to IND filing date. The test compound prepared outside of Ricerca could not be properly formulated and the quantity was less than needed for the dog study.

To meet the IND filing deadline, the client asked Ricerca to characterize the existing API and identify the cause of the formulation problems, to reprocess the lot, if necessary, and to prepare additional material to ensure the study could be completed. Ricerca fielded a team of process chemists, analytical chemists, and biologists. The Ricerca project manager maintained daily contact with the client to ensure the plan was executed and that the study could continue as planned.

The formulation problem was traced to a process change at the manufacturer of the API, which brought in previously unknown impurities. A reprocessing method to remove the impurities and a mechanism for their formation/control was determined. New lots of the API were made by Ricerca, using the process knowledge gained in this work.

RESULTS

The old lot was reprocessed and new material made. The toxicology study was completed and the client met his original IND filing date.

For detailed comments from the client, please contact Ricerca's Business Development Team at 440-357-3300.