

Develop Enabling Formulation for Animal Health Client

A top ten animal health company whose products target and treat some of the most harmful animal diseases. This client develops health products across the board from companion animal to food animal treatments and drug therapies.

Singota Solutions has been working with this client for over four years in service areas that include supply chain, production, development, and analytical testing.



Problem

The client was in early stage development for a drug product to be used to treat a condition commonly seen in a large food animal. This condition causes several problems for these animals and their producers including increased waste, decreased production, extra labor, and costs associated with these issues. The client is evaluating a new administration form of the drug product to treat this condition. To begin they only had an API and no existing formulations. The client came to Singota to develop and evaluate possible formulations, and to optimize the formulations for several factors including viscosity, density, freezing point depression, drug delivery, and pH, while keeping in mind and avoiding possible manufacturing hurdles.

Solution

Singota was able to suggest a range of possible excipients that would create unique formulations to meet the client needs, and working together with the client Singota was able to develop over forty formulations. In only four months, Singota was able to formulate and analyze all forty formulations which were subsequently used in in-vitro studies for further characterization. Using all of the combined data, Singota worked with the client to determine three formulations that were optimized in all of the identified factors such as viscosity, freezing point, delivery, etc. Singota has also helped the client move forward in the development process by producing several small aseptic batches of the formulations to be used in pharmacokinetic studies, accelerated stability, and small clinical studies.

Impact

Singota was able to move quickly and help move the client from no formulation to having multiple lead formulations in a very short amount of time. Due to this work, the client will be able to continue clinical studies and determine the feasibility of moving this product forward along the drug development pathway. Singota continues to support this project with ongoing stability testing as well as producing material for ongoing in-vivo testing.