

5th International Conference and Exhibition on

Pharmaceutics & Novel Drug Delivery Systems

March 16-18, 2015 Crowne Plaza, Dubai, UAE

Solid state formulation of therapeutic antibodies using spray drying for reconstitution

Ramesh S Kashi², Michael P Burke¹, Jeffrey F Breit¹, Devon B DuBose¹, David Lyon¹ and Yunsong (Frank) Li²

¹Bend Research Inc., ²Merck and Co. Inc.

The development of high concentration antibody solutions is being explored for use both in material logistics and storage as well as for clinical application. The design of a robust and high performing solid state formulation platform using a spray dry manufacturing process requires the optimization of spray drying attributes (i.e. nozzle selection and flow rates) and selection of appropriate formulation/excipient components including low molecular weight sugars, buffers and surfactants. Spray drying know-how and an understanding of the protein's inherent stability can streamline the optimization of these attributes. A historical review of research efforts in this area reveals themes around process and formulation, but a well characterized platform incorporating process, formulation, and an understanding of protein chemistry is absent. We present a case study wherein we begin dissecting the variables important for the development of a spray dried antibody formulation with a focus on drying kinetics, excipients and protein stability. The desirable attributes of resuspended antibody solutions that we focused on in our study included a clear solution with minimal sub-visible aggregates, while maintaining antibody integrity as compared to a non-spray dried sample. Solid state as well as wet lab analytics were utilized in this study. Utilizing the information accrued in this program and other similar programs we have developed a model for platform development of a spray dried monoclonal antibody formulation.

Biography

Ramesh Kashi currently is a Sr. Principal Scientist in the Bioprocess Technology and Expression Group at Merck & Co. NJ, USA. He is responsible for external collaborations, scouting and evaluation of novel formulation and delivery technologies for biologics. Ramesh has 25+ years of biotech experience in early and late stages of drug product development and commercialization of biopharmaceuticals. Prior to joining Merck in 2006, he held various scientific and leadership positions at Agenus, Baxter Bioscience, Diagnostic Product Corp., and Biogen. Ramesh received PhD in Biochemistry from Indian Institute of Science and conducted post-doctoral studies at Harvard and Tufts Medical Schools.

ramesh.kashi@merck.com