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Strategies to improve dissolution rate of lyophilized high dose protein formulations

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There is an increasing interest in formulation development of lyophilized proteins and monoclonal antibodies at high concentration. Development of high dose protein formulations is often associated with challenges such as slow dissolution of the lyophilized cake, poor syringeability, aggregation and thus poor stability after reconstitution. The latter becomes a major concern especially for the development of multi-dose formulations that may require several days of post-reconstitution stability, especially considering the protein preservative interactions. In this presentation the important parameters for improving dissolution of lyophilized protein cakes are discussed. Especial attention is paid towards dissolution of high dose protein formulations in dual chamber syringes, and strategies to improve dissolution rate of the lyophilized cakes in general.

Biography

Mitra Mosharraf received her MSc in Pharmacy and her PhD in Pharmaceutical Sciences from Uppsala University. Prior to joining HTD Biosystems as the Chief Scientific Officer, she held different positions at Pharmacia and Pfizer, where she was actively involved in the formulation development of protein drugs. She has several scientific publications in peer-reviewed journals in the areas of protein formulation, solubility and dissolution rate of sparingly soluble drugs and a patent on manufacturing crystals of growth hormone. She has also been an invited Lecturer in Pharmaceutics at the Department of Pharmacy, Uppsala University on a regular basis.

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