

Case Studies and Examples of Biopharmaceutical Modalities Processed by Bulk Crystallization or Bulk Freeze-Drying

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Introduction

While the previous chapter describes the basic principle, process development, and scale-up aspects of both bulk crystallization and freeze-drying in general, this chapter describes unique examples of biopharmaceuticals processed by these techniques. A section of this chapter describes in detail the processing approach for human insulin—the world's first approved recombinant biotherapeutic. In the case of insulin, the purified biologic is generally bulk crystallized using certain crystallization aids and finally freeze-dried to ultimately minimize the residual moisture content. This approach has also been extended to certain modifications of insulin and insulin analogs. The next class of biotherapeutics discussed in this chapter are monoclonal antibodies (mAbs) and antibody fragments. Bulk crystallization has been used for several aspects of antibody therapeutic development, including an efficient capture and purification strategy, long-term storage, and high concentration formulation development strategy. The third group of modalities discussed in this chapter are examples like aprotinin and L-methionine γ -lyase which have been crystallized for process and drug development purposes. Bulk freeze-drying has recently also been applied in plasma and plasma fraction product development.

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