Current Trends and Advances in Bulk Crystallization and Freeze-Drying of Biopharmaceuticals

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Introduction

Drug discovery, design, and development process in the post genomics era has changed significantly with an increasing number of approvals for recombinant therapeutics. Such recombinant therapeutics include varied modalities such as enzymes, replacement hormones (e.g., growth hormone, insulin), growth factors, cytokines, fusion proteins, monoclonal antibodies (mAbs), vaccines, nucleic acid-based therapeutics, and antibody–drug conjugates [6, 14]. The pharmaceutical development of these varied modalities has further enhanced our understanding in several platform development processes and manufacturing techniques. The aforementioned biopharmaceutical modalities are marketed in different forms such as liquid products, solid lyophilized formulations, and several device combinations. Protein stability is a principle factor governing the ultimate form and configuration for these commercial biopharmaceuticals [30, 31, 56]. Designing stable liquid prototype formulations is generally the first step towards development of a novel biopharmaceutical; moreover, this approach has been adequately reviewed and routinely applied in the biopharmaceutical industry [54]. Design of a stable lyophilized formulation is an alternative (and often parallel or overlapping) approach taken during product development [7, 55]. Lyophilization, to date, remains a popular means of converting proteins into solid form to achieve reasonable shelf life as a commercial pharmaceutical product. The broader concept of drug product lyophilization and related aspects such as excipient selection and buffer composition, container closure systems, and

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