on the loading configurations and freeze-dry cycle utilized. Therefore, appropriate optimization studies are needed to develop a successful, robust freeze-dry cycle. Control of moisture for the product at the end of drying, after sealing, and absorption from the package (i.e., from the closure or diluent chamber) during the product shelf life must be evaluated and correlated to product stability. Specifications need to be established, which cover each chamber separately and the combined reconstituted product. The benefits of dual chamber lyophilized products compared to standard vial packages will need to be evaluated based on a variety of factors such as total production cost for the units required for dose administration, ease-of-use by the consumer, increased safety/sterility assurance, etc.

REFERENCES

1. Michaels TM Jr. Dual chamber prefilled syringes. J Parenter Sci Tech 1988; 42: 199–202.
2. Executive summary. In: Drug Delivery Pens and Autoinjectors: Devices, Diseases, and Delivery Strategies: Applied Data Research, 2007:6.
3. Pollin J. The ins and outs of prefilled syringes. Pharm Med Packaging News 2003; 11:40–44.
4. French D, Masters S. Current trends in the injection of biopharmaceuticals. Am Pharm Rev 2005; 8:30–37.
5. Executive summary. In: Pen Injectors: Worldwide Markets and Therapies. Amherst, New Hampshire: Greystone Associates, 2006:3.
6. Cotten J. Current market and key trends of devices used in self-injection. In: Furness G, ed. Prefilled Syringes: the Trend for Growth Strengthens. West Sussex: ONDrugDelivery Ltd, 2005:25–27.
7. Solomun L, Ibric S, Boltic Z, et al. The impact of primary packaging on the quality of parenteral products. J Pharm Biomed Anal 2008; 48:744–748.
8. Colandene J, Maldonado L, Creagh A, et al. Lyophilization cycle development for high-concentration monoclonal antibody formulation lacking a crystalline bulking agent. J Pharm Sci 2007; 96:1598–1608.
9. Rowles B, Sperandio GJ, Shaw SM. Effects of elastomer closures on the sorption of certain 14C-labeled drug and preservative combinations. Bull Parenter Drug Assoc 1971; 25:2–22.
10. Wang Y, Chien Y. Sterile pharmaceutical packaging: compatibility and stability. In: Technical Report No 5, Parenteral Drug Association, Inc., 1984:107–125.
11. Mundry T. Einbrennsilikonisierung Bei Pharmazeutischen Glaspackmitteln—Analytische Studien eines Produktionsprozesses. Berlin, Germany: Humoldt Universitaet, 1999.
12. Mundry T, Schurreit T, Surmann P. The fate of silicone oil during heat-curing glass siliconization-changes in molecular parameters analyzed by size exclusion and high temperature gas chromatography. PDA J Pharm Sci Technol 2000; 54:383–397.
13. Gabrielson J, Bates DG, Williams BM, et al. Silicone oil contamination of therapeutic protein formulations: surfactant and protein effects. Abstracts of Papers, 234th ACS National Meeting, Boston, MA, United States, August 19–23, 2007:BIOT-227.
14. Jones LS, Kaufmann A, Middaugh CR. Silicone oil induced aggregation of proteins. J Pharm Sci 2005; 94:918–927.
15. Chantelau E. Silicone oil contamination of insulin. Diabet Med 1989; 6:278.
16. Rosenburg A. Effects of protein aggregates: an immunologic perspective. AAPS J 2006; 8:E501–E507.
17. Schellekens H. Immunogenicity of therapeutic proteins: clinical implications and future prospects. Clin Ther 2002; 24:1720–1740; discussion 19.
18. Overcashier DE, Chan EK, Hsu CC. Technical considerations in the development of prefilled syringes for protein products. Am Pharm Rev 2006; 9:77–83.