

Evaluating B2-Coating as an Alternative to Silicone Oil

I. Overview

In an effort to support customers of West Pharmaceutical Services who may be evaluating B2-Coating as an alternative to silicone oil on an already approved drug product, West Pharmaceutical Services' Technical Customer Services Group lists the following factors to help you decide what may be appropriate in your evaluation and submission processes.

- 1.) B2-Coating is a polymerized, silicone coating. The polymeric structure and backbone of the coating is, therefore, very similar to traditional silicone oil. There is a Drug Master File on this coating that the FDA can refer to upon receipt of your submission. Contact West's Regulatory Group for an authorization letter allowing access to this DMF. Additionally, West has conducted specialized Intracutaneous and Systemic toxicity testing of the coating and its high molecular weight silicone components. A summary of this work can be found in West's Technical Report # 2000/038.
- 2.) In addition to the benefits that are normally found with silicone oil coated closures (lubricity and processability) the B2 minimizes the characteristics associated with the silicone oil treated stoppers (particles in solution, inconsistent application). Various technical reports detailing the characteristics of B2-Coating are available from West's Technical Customer Services Group.
- 3.) The extractable profile of your B2 coated closure should be equivalent against a comparable silicone oil coated closure. Although the B2-Coating is not presented to the market as having "barrier" characteristics, testing has shown the coating to exhibit lower extractables.
- 4.) It is recommended that, should you be moving from a silicone oil treated West formulation to a B2 coated version of the same formula, you generate real-time and accelerated stability data. At the completion of the accelerated study, the suitability of the coating for future product use should be determined. Notification of the regulatory agency at this time is suggested.

II. Summary

The information given in this Technical Support Bulletin is to be used as a general reference guide only. West Pharmaceutical Services warrants that its services will be performed according to all specified methods and testing procedures, including current Good Manufacturing Practices, where applicable. West Pharmaceutical Services' products are sold on the basis that it is the customer's responsibility to evaluate and test the West product to determine its compatibility with other materials and fitness for any end use.

This technical bulletin dated 26 January 1999, supersedes any other previously released versions of this bulletin.

B2-Coating technology is licensed from Daikyo Seiko, Ltd.

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Bass and Spangenberg
v.
Fresenius Kabi USA, LLC
U.S. Patent No. 8,476,010
Exhibit 1011