

Summary

The potential of the test article, HARD CLAD OPTICAL FIBER, Lot: B042409A-1, to cause irritation following intradermal injection in rabbits was evaluated based on the International Organization for Standardization 10993-10: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was extracted in 0.9% sodium chloride USP solution (SC) and sesame oil, NF (SO). A 0.2 mL dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each of two rabbits. Similarly, the corresponding control was injected on the left side of the back of each rabbit. The injection sites were observed immediately after injection. Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection.

Under the conditions of this study, there was no erythema and no edema from the SC test extract injected intracutaneously into rabbits. There was very slight erythema and very slight edema from the SO test extract injected intracutaneously into rabbits. Each test article extract met the requirements of the test since the difference between the test extracts and corresponding control mean score was 1.0 or less.

Study and Supervisory

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Date Completed

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