



Biocompatibility Assessments of Surgical sutures: The Guinea Pig Maximization Test

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Abstract : Surgical suture is a medical device used to hold body tissues together after an injury or surgery. Application generally involves using a needle with an attached length of thread as evaluated for the potential to cause delayed skin contact sensitization in a Closed-patch test. This study was conducted base on the requirements of ISO 10993-10: Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization. The guinea pig maximization test (GPMT) is made of the potential of the material under test to produce skin sensitization. The polar and nonpolar extracts were prepared by using saline solution and olive oil, respectively, after sinking the materials tested (2.0 g) in 10 ml of the corresponding liquid. Incubation was carried out at the temperature of 37 °C for 72 h. The saline solution and pure olive oil were used as negative control samples and were incubated under the same conditions as above. The guinea pig maximization test (GPMT) consist of intradermal induction phase, topical induction patches and challenge phase. Following a intradermal induction phase, The test item extract with polar and non polar solvent were injected in clipping area of each animal in test group and control group, respectively. Following a challenge phase, the test group and control group were challenged with the test item. No evidence of sensitization was observed. Individual results of skin scoring for the induction phase and the challenge phase is 0.0.

Keyword : Surgical suture, Intravenous reactivity test.

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