Certificate Of Compliance
With ISO 10993
Biological Evaluation Of Medical Devices

Test Facility:

NAMSA
6750 Wales Road
Northwood, OH 43619

Sponsor:

Ralph Peltier
ME-92 Operations, Inc.
10 Houghton Street
Providence, RI 02904

Test Article:

ME-92 coated coupon 304SS

Identification No.

Lot #38408

NAMSA Lab No.

14T_27530_10

COMPLETED TESTS Page

ISO 10993-1: Selection of Tests

The device was received on March 5, 2014. It was categorized as being an externally communicating device - blood path, indirect with a contact duration of limited (≤ 24 hours) and evaluated according to this standard.

ISO 10993-2: Animal Welfare

Animal care, housing and treatments met or exceeded the requirements of this standard.

ISO 10993-12: Sample Preparation

Test sample extracts were prepared according to specification in this standard. Details are noted for each test listed.

ISO 10993-5: Tests for Cytotoxicity

Cytotoxicity Study by Elution

The test article was prepared at a ratio of 120 cm^2:20 mL, and extracted in minimal essential medium at 37°C for 24 hours. This test extract was placed onto three separate confluent monolayers of L-929 mouse fibroblast cells propagated in 5% CO_2. All monolayers were incubated at 37°C in the presence of 5% CO_2 for 48 hours. The monolayer in the test, reagent control, negative control and positive control wells was examined microscopically at 48 hours to determine any change in cell morphology. The test article cytotoxicity grade was 0. The requirements of the test were met.

ISO 10993-10: Tests for Irritation and Delayed-Type Hypersensitivity

Maximization Sensitization Study

The test article was prepared based on a ratio of 120 cm^2:20 mL, and extracted in SC and SO at 121°C for 1 hour. Each extract was intradermally injected (I) and occlusively patched (II) to ten test guinea pigs (per extract) in an attempt to induce sensitization. Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the reagent control. All sites were scored at approximately 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization.

Intracutaneous Reactivity Study

The test article was prepared based on a ratio of 120 cm^2:20 mL, and extracted in SC and SO at 121°C for 1 hour. 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 rabbit. Similarly, the corresponding reagent control was injected on the left side of the back of each rabbit. The injection sites were observed for erythema and edema after injection and at 24, 48 and 72 hours after injection. There was no to very slight erythema and no edema. The test article met the requirements of the study.

ISO 10993-11: Tests for Systemic Toxicity

Acute Systemic Toxicity Study

The test article was prepared based on a ratio of 120 cm^2:20 mL, and extracted in SC and SO at 121°C for 1 hour. A single dose of the appropriate test article extract was injected into each of five mice per extract. The animals were observed immediately and at 4, 24, 48, and 72 hours after systemic injection. The animals were weighed immediately prior to dosing and daily for three days after dosing. No mortality or evidence of significant systemic toxicity was noted. The test article met the requirements of the study.

Material Mediated Rabbit Pyrogen Test

The test article was prepared based on a ratio of 120 cm^2:20 mL, and extracted in 0.9% Sodium Chloride Solution, USP at 121°C for 1 hour. A single dose of the test article extract was injected into each of three rabbits via the marginal ear vein. Body temperatures were recorded at 0 time and at 60, 90, 120, 150, and 180 minutes post injection. The test article was determined to be non-pyrogenic.

Hemolysis Study by ASTM

The test article was prepared based on a ratio of 120 cm^2:20 mL, extracted in calcium and magnesium-free phosphate buffered saline (CMF-PBS) at 121°C for 1 hour. Blood was obtained from three rabbits, pooled, diluted and added to triplicate tubes of the test article extract and triplicate tubes of the test article in CMF-PBS to be tested as the direct contact. The tubes were then maintained in a stationary position for at least 3 hours at 37°C. Following incubation, the suspensions were centrifuged and the resulting supernatant was added to Drabkin's reagent. The absorbance of the extract was spectrophotometrically measured at a wavelength of 540 nm. The test article extract was considered nonhemolytic. The test article in direct contact was considered nonhemolytic.

Approved by Arizona Eugene Carter Date 04-21-14

Arizona E. Carter, BS, ALAT
Technical Reviewer