CERTIFICATE

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Henkel Corporation
One Henkel Way
Rocky Hill, Connecticut 06067

CONFIDENTIAL

STUDY TITLE

Summary Certificate of ISO 10993 Testing - Biological Evaluation of Medical Devices

TEST ARTICLE NAME

Loctite 402

TEST ARTICLE IDENTIFICATION

Lot #23884712

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 6 cm^2:1 mL, and extracted in single strength Minimal Essential Medium at 37°C for 24 hours. This test extract was placed onto three separate subconfluent 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 grades were grade 4 for the undiluted test extract and the 50% dilution, a grade 1 for the 25% dilution and a grade 0 for and 12.5% dilution. The undiluted test article extract and the 50% dilution did not meet the requirements of the test, but the 25% and 12.5% test article extract dilutions did meet the requirements of the test.

ISO 10993-23: Tests for Irritation

Intracutaneous Reactivity Study

The test article was prepared based on a ratio of 6 cm^2:1 mL, and extracted in 0.9% sodium chloride USP solution (SC), sesame oil, NF (SO), alcohol in saline (AS) and polyethylene glycol (PEG) at 50°C for 72 hours. 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. 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 6 cm^2:1 mL, and extracted in 0.9% sodium chloride USP solution (SC), sesame oil, NF (SO), alcohol in saline (AS) and polyethylene glycol (PEG) at 50°C for 72 hours. 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.

ISO 10993-4: Selection of Tests for Interactions with Blood

Hemolysis Study by ASTM

The test article was prepared based on a ratio of 6 cm^2:1 mL, extracted in calcium and magnesium-free phosphate buffered saline (CMF-PBS) at 50°C for 72 hours. Blood was obtained from three rabbits, pooled, diluted and added to triplicate tubes of the test article extract. The polystyrene containers were then maintained in a stationary position with periodic inversions 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.

ISO 10993-6: Tests for Local Effects after Implantation

Muscle Implantation Study

Previously sterilized test and control samples were aseptically prepared. Three rabbits were implanted with a minimum of four test and four control samples each and were then euthanized 2 weeks later. Muscle tissues were excised and the implant sites were examined macroscopically. Following histological preparation, a microscopic evaluation of representative implant sites from each rabbit was conducted to further define any tissue response.

The macroscopic reaction was not significant as compared to the negative control. Microscopically, the test article caused a minimal or no as compared to the negative control.

Approved by: Natalie N. Stoian — 12 Jul 2023

Natalie N. Stoian, PhD
Senior Technical Reviewer

Date