

Test Article:

Loctite 4314

Identification No.

Batch# L30AAB6687

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR:

Henkel Corporation
One Henkel Way
Rocky Hill, CT 06067

Summary Test Certificate

Biological Evaluation of Medical Devices

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Completed Tests

ISO 10993-2:	Animal Welfare
ISO 10993-12:	Sample Preparation
ISO 10993-5:	Tests for Cytotoxicity
ISO 10993-10:	Tests for Irritation and Delayed-Type Hypersensitivity
ISO 10993-11:	Tests for Systemic Toxicity
ISO 10993-4:	Selection of Tests for Interaction with Blood
ISO 10993-6:	Tests for Local Effects after Implantation



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 6 cm²:1 mL, and extracted in 1X MEM 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% CO₂. All monolayers were incubated at 37°C in the presence of 5% CO₂ 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 4 (100%), 1 (50%) and 0 (25%). The undiluted test article extract did not meet the requirements of the test. The 25% and 50% test article extract dilutions met the requirements of the test.

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

Intracutaneous Reactivity Study

The test article was prepared based on a ratio of 6 cm²:1 mL, extracted in SC SO AS 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 test.

ISO 10993-11: Tests for Systemic Toxicity

Acute Systemic Toxicity Study

The test article was prepared based on a ratio of 6 cm²:1 mL, extracted in SC SO AS 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 the three days after dosing. There was no mortality or evidence of systemic toxicity. 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 cm²:1 mL, extracted in 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 4 test and 4 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 minimum reaction as compared to the negative control article.

Approved by


Arizona E. Carter, BS, ALAT

Date

06-23-20