Certificate of Compliance
With ISO 10993
Biological Evaluation of Medical Devices

Test Facility:

NAMSA
6750 Wales Road
Northwood, OH 43619

Sponsor:

Julie Coney-Sloop
Novation iQ
9806 Lackman Road
Lenexa, KS 66219

Test Article:

Novation iQ white polyolefin
foam

Identification No.

N216H2-04-05-05

NAMSA Lab No.

16T_59006_09

COMPLETED TESTS Page

ISO 10993-1: Selection of Tests

The device was received on September 6, 2016. It was categorized as being a surface device with a contact duration of permanent (>30 days) 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 Agarose Overlay

The test article was cut into a 1 cm x 1 cm portion. The test article was placed on triplicate agarose surfaces directly overlaying confluent monolayers of L-929 mouse fibroblast cells. After incubating at 37°C in 5% CO_2 for 24 hours, the cell culture was examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). The cultures were then examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the articles. The test article cytotoxicity grade was 1 (slight reactivity). The requirements of the test were met.

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

Closed Patch Sensitization Study

The test article was occlusively patched for 6 hours (± 30 minutes) to the intact skin of 10 guinea pigs, three times a week, for a total of nine induction treatments over a 3 week period. The control article was similarly patched to 5 guinea pigs. Following a recovery period, all animals received a challenge patch of the test article and the control article. Dermal sites were evaluated at approximately 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization.

Skin Irritation Study

Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after a single application. No erythema and no edema were observed on the skin of the rabbits. The response of the test article was categorized as negligible.

ISO Oral Mucosal Irritation Study in Hamsters-Collar Method-7 Day

The right cheek pouch of ten hamsters was implanted with the test article. The left cheek pouch of all ten animals was implanted with polymethylmethacrylate discs which served as the control. Articles were held in place with fitted collars. After 7 days of exposure, the animals were euthanized. The pouch mucosa were removed and evaluated macroscopically and microscopically. The test article was considered a nonirritant to the oral mucosa of the hamster.

Ocular Irritation Study

The test article was prepared based on a ratio of 3 cm^2:1 mL, and extracted in 0.9% sodium chloride (SC) and sesame oil (SO) at 70°C for 24 hours. A 0.2 mL dose of the appropriate test article extract was instilled in the right eye of three test rabbits. Similarly, the corresponding reagent control was instilled into the left eye of each rabbit as the control. Ocular reactions were evaluated at 1, 24, 48, and 72 hours after the single exposure. There was no evidence of significant irritation in the test eye or control eye of any rabbit. The SC and SO test article extracts would not be considered irritants to the ocular tissue of the rabbit.

Approved by Krystle M. Campbell Date 1-24-17

Krystle M. Campbell, BS
Medical Research Manager