VERTEC FK79 BIOCOMPATIBILITY

Technical Datasheet

TEST METHOD

Cytotoxicity – ISO 10993-5, Biological evaluation – part 5: Tests for in vitro cytotoxicity.

TEST SUMMARY

The potential biological reactivity of a mammalian cell culture (mouse fibroblast L929) in response to exposure to the extract of the test article, Thermoplastic Elastomer (TPE), PFV FK79* film, was determined. The test article was extracted in Minimum Essential Medium (MEM) with 10% Fetal Bovine Serum (referred to as complete MEM) for 24 ± 2 hours at 37 ± 1 °C. Negative and positive controls were prepared similarly. The maintenance medium of L929 cells grown in 6-well plates was replaced with the 100% (neat) extracts in 3 replicates, and the cells were incubated for 48 ± 2 hours at 37 ± 1 °C. The biological reactivity of the cells following the exposure to the extracts was visually observed with a microscope, and graded on a scale of 0 to 4.

RESULT

There was no biological reactivity (Grade 0) of the cells exposed to the test article extract. The response obtained from the positive and negative control article extracts confirmed the suitability of the test system.

Based on the criteria of the protocol and the ISO 10993-5 guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic effect.

REFERENCES

• ISO 10993-5, 2009, Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity.

• ISO 10993-12, 2021, Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials.

• ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

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