Designation: F 749 – 98 (Reapproved 2002)ε2

Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit[1]

This standard is issued under the fixed designation F 749; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε[1] NOTE—Footnote 3 was editorially corrected in November 2002.
ε[2] NOTE—Footnote 4 was editorially corrected in December 2002.

1. Scope

1.1 This practice is a nonspecific, acute toxicity test used to help determine the biocompatibility of materials used in medical devices.

1.2 The liquids injected in the rabbits are those obtained by Practice F 619 where the extraction vehicles are saline, vegetable oil, or other liquids simulating human body fluids.

1.3 This practice is one of several developed for the assessment of the biocompatibility of materials. Practice F 748 may provide guidance for the selection of appropriate methods for testing materials for a specific application.

1.4 The values stated in SI units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

F 619 Practice for Extraction of Medical Plastics[2]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[2]

3. Summary of Practice

3.1 The extract liquid is prepared in accordance with Practice F 619. The extraction vehicles are saline and vegetable oil, or other extraction vehicles can be used, as described in Practice F 619. The extract liquid is injected into rabbits and the animals are observed at regular intervals for 72 h for erythema, edema, and necrosis.

4. Significance and Use

4.1 This practice is to be used to help assess the biocompatibility of materials used in medical devices. It is an acute toxicological test designed to detect the presence of injurious leachable substances.

4.2 This practice may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the method in view of the materials being tested, their potential applications, and the recommendations contained in Practice F 748.

4.3 The only limitation applicable is the extract preparation. Refer to Sections 4.3 and 4.4 of Practice F 619 for a description of this limitation.

5. Apparatus

5.1 *Cages*—There shall be one cage for each rabbit exposed to one extract liquid. Each rabbit will be uniquely identified with this identity recorded.

5.2 *Syringes*—Sterile syringes, not greater than 2 mL in volume, with a precision of no less than ±0.10 mL shall be used. Sterile needles of 21 to 26 gage shall be used.

6. Test Animals

6.1 *Rabbits*—The rabbits shall be thin-skinned albino type, healthy, and not previously used for any test. Animal care shall be in accordance with Guide for Care and Use of Laboratory Animals.[3] Rabbits with significant scars or wounds are not suitable for this test. For each extraction vehicle a minimum of two rabbits are used in the test. If the results of the first test are inconclusive, three more rabbits are needed to complete the test with that extraction vehicle for one material.

6.1.1 During the test the rabbits shall be fed normally, with commercially available feed and tap water.

7. Sampling

7.1 Sample in accordance with Practice F 619.

8. Sample and Test Specimen

8.1 The sample is the extract of the test article (that is, plastic or other material) exposed to the extraction procedure.

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

Current edition approved February 10, 1998. Published June 1998. Originally published as F 749 – 82. Last previous edition F 749 – 87 (1996)ε1.

[2] *Annual Book of ASTM Standards*, Vol 13.01.

[3] *The Guide for Care and Use of Laboratory Animals*, Institute of Laboratory Animal Research Publication. Available from National Academy Press, 500 Fifth St., NW, Lockbox 285, Washington, DC 20055.