Designation: F750 – 87 (Reapproved 2012)

Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse[1]

This standard is issued under the fixed designation F750; 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.

1. Scope

1.1 This practice covers a nonspecific, acute toxicity test used for detecting leachables from materials used in medical devices.

1.2 The liquids injected into the mouse are those obtained by Practice F619 where the extraction vehicles are saline, vegetable oil, or other liquids simulating human body fluids.

1.3 Two procedures are outlined: Method A for intravenous injection and Method B for intraperitoneal injection.

1.4 This practice is one of several developed for the assessment of the biocompatibility of materials. Practice F748 may provide guidance for the selection of appropriate methods for testing materials for a specific application.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F619 Practice for Extraction of Medical Plastics

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

3. Summary of Practice

3.1 The extract liquid is prepared in accordance with Practice F619. The extraction vehicles are saline and vegetable oil, or other extraction vehicles, as described in Practice F619. The extract liquid is injected into mice, and the animals are observed at regular intervals for 72 h for reactions, survival, etc.

4. Significance and Use

4.1 This practice is intended 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 F748.

4.3 The only limitation applicable is the extract preparation. Refer to Sections 4.3 and 4.4 of Practice F619 for a description of this limitation.

5. Apparatus

5.1 *Mice*—The mice shall be albino-type, healthy and not previously used, and shall weigh between 17 and 23 g. Animal care shall be in accordance with the "Guide for Care and Use of Laboratory Animals."[3] Age, sex, and weight shall be recorded and reported. All the mice for each extraction vehicle shall be from the same source. For each extraction vehicle, a minimum of ten mice are used in the test. If the results of this first test group are inconclusive, then 20 more mice will be needed to complete the test of one extraction vehicle for one plastic.

5.1.1 During the test the mice shall be fed normally with commercially available feed and tap water.

5.2 *Cages*—There shall be one cage for the five mice exposed to one extract liquid. Each mouse in a cage shall be uniquely identified, and this identification shall be recorded. Male and female mice shall be housed separately, and their cages are positioned in a manner which prevents the accidental transfer of feces or bedding from cage to cage.

5.3 *Syringe*—Sterile syringes, not greater than 3 mL in volume, with a precision of ±0.10 mL shall be used.

5.3.1 *Method A*—Sterile needles of 25 to 27½ gage shall be used.

[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.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] U.S. Department of Health, Education, and Welfare, *Guide for Care and Use of Laboratory Animals*, Publication No. NIH 78-23, Bethesda, MD, 1978.

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