Designation: F 719 – 81 (Reapproved 2002)ε1

Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation[1]

This standard is issued under the fixed designation F 719; 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—Editorial changes were made throughout in June 2002.

1. Scope

1.1 This practice covers a procedure by which the irritancy of a biomaterial may be assessed through contact with abraded and intact skin of rabbits.

1.2 The results of this practice depend upon the effectiveness with which contact between skin and the test material is established and maintained. Because of the operator technique included in performing this test, it is important that the test be performed by personnel with appropriate training.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

F 619 Practice for Extraction of Medical Plastics[2]

3. Summary of Practice

3.1 Exposure of skin to the test material is accomplished by means of a patch test technique employing two intact and two abraded sites on the back of each of six albino rabbits. The skin is clipped free of hair one day prior to testing. The test substance is applied using 0.5 mL for liquids, 0.5 g for solids or semisolids, and a 2.5 by 2.5-cm square patch for films. After application, each test site is covered with a 2.5 by 2.5-cm gauze flat, and the entire trunk is occluded with a polyethylene sleeve. After 24 h, the sleeve, flat, and test material are removed, and test sites are evaluated for erythema and edema.

4. Significance and Use

4.1 Materials that are to be in contact with the skin should not cause irritation to the skin. Since it is probably the substances leached from a material that cause the irritation, this practice provides for direct material-skin contact testing or for skin exposure to the liquid extract of the test material. The rationale for this rabbit test is that it is a comparatively quick and inexpensive method which, through use over the years, has become a generally accepted method.

5. Materials and Manufacture

5.1 *Young New Zealand Albino Rabbits*,

5.2 *Gauze Flats*, 2.5 by 2.5-cm,

5.3 *Polyethylene Sleeves*, extra clear, and

5.4 *Adhesive Tape*, ½-in.

6. Test Specimen

6.1 The test specimen may be one of three forms:

6.1.1 Test 0.5 mL of liquids or saline extract liquids obtained in accordance with Practice F 619.

6.1.2 Test 0.5 g of solids or semisolids.

6.1.3 Test films 2.5 by 2.5 cm.

NOTE 1—A vehicle control for liquids is required because of the potential for false positive due to skin temperature changes when handling rabbits. Positive controls may be used to validate the test method. The use of 5 % procaine HCl as a positive control is suggested.[3]

6.2 The pH of the solutions should be measured and reported, if appropriate.

7. Procedure

7.1 *Preparation of Test Animals*:

7.1.1 Twenty-four hours before the test, clip the hair from the backs of the animals so as to expose two test areas on each side of the spine, which are 10 cm apart.

7.1.2 To obtain more effective contact between the skin and the test substance, it may be necessary to use a nonirritating depilatory agent. This test method may be used to ensure that the depilatory agent is nonirritating.

7.1.3 Test sites may be designated as two on each side of the spine. Alternatively, the area may be divided into quadrants with test and control substances applied to each quadrant.

7.2 *Test 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.

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

[3] H. H. Draize, *Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics*, 1965, p. 46.