Designation: F720 – 81(Reapproved 2007)ε1

Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test[1]

This standard is issued under the fixed designation F720; 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.

ε1 NOTE—Formatting and grammar were corrected editorially throughout in April 2007.

1. Scope

1.1 This practice is intended to determine the potential for a substance, or material extract, to elicit contact dermal allergenicity.

1.2 *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:*[2]

F619 Practice for Extraction of Medical Plastics

3. Summary of Practice

3.1 After a two-stage induction employing Freund's complete adjuvant and sodium lauryl sulfate, the substance or extract is placed on patches and then placed on the skin of guinea pigs. After 24 h, the patches are removed and the skin examined for allergic reaction, and the intensity of the reaction scored at the time of removal and 24 and 48 h subsequent to removal.

4. Significance and Use

4.1 In selecting a new material for human contact in medical applications, it is important to ensure that the material will not stimulate the immune system to produce an allergic reaction. The reaction would be due to substances which could leach out of a material. Therefore, this practice provides for using material extracts. The rationale for this practice is based on the fact that the guinea pig has been shown to be the best animal model for human allergic contact dermatitis. The use of Freund's complete adjuvant and sodium lauryl sulfate tends to enhance the potential of a material to cause an allergy. Therefore, this test, while not guaranteeing that a material is nonallergenic, is the most severe animal test in common use today.

5. Materials and Manufacturer

5.1 *Hartley Strain Guinea Pigs,* male, 300 to 500 g.

5.1.1 Ten animals are used for each test material.

5.2 *Freund's Complete Adjuvant.*

5.3 *Occlusive Surgical Tape,* 3.75 cm in width.

5.4 *Elastic Bandage.*

5.5 *Sodium Lauryl Sulfate* (10 weight %) in USP petroleum jelly.

5.6 *Positive Control Substance.*

5.6.1 5 % formaldehyde for water-soluble test substances.

6. Preparation of Test Samples

6.1 *Samples for Intradermal Injection:*

6.1.1 *Water-Soluble Constituents or Water Extract Liquids:*

6.1.1.1 Dissolve the water-soluble constituent up to its maximum solubility, not to exceed a concentration of 10 weight %, or obtain a water extraction liquid as described in Practice F619.

6.1.1.2 Combine equal volumes of the liquid described in 6.1.1.1 and Freund's complete adjuvant. Homogenize by continuous and vigorous vortex mixing for a minimum of 5 min. Emulsification is complete when a drop placed on the surface of a water-ice bath remains intact.

6.1.1.3 Also prepare the constituent or extract to the same concentration in water without Freund's complete adjuvant.

6.1.2 *Oil Soluble Constituents:*

6.1.2.1 Dissolve oil-soluble constituents in Freund's complete adjuvant to concentration of 10 weight %.

6.1.2.2 Combine equal volumes of the 10 % Freund's adjuvant solution with an equal volume of water by slowly adding the water to the adjuvant while homogenizing with a rotating stirrer. Homogenize by continuous and vigorous mixing for a

[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 Feb. 1, 2007. Published February 2007. Originally approved in 1981. Last previous edition approved in 2002 as F720 – 81 (2002)ε1 . DOI: 10.1520/F0720-81R07E01.

[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.