



Standard Practice for Extraction of Medical Plastics¹

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ε¹ NOTE—Keywords were added editorially in May 1998.

1. Scope

1.1 This practice covers methods for extraction of medical plastics in liquids that simulate body fluids in their action on the plastics. This practice identifies two methods of extraction: one used for obtaining “extract liquid” to be analyzed by chemical and physical tests; and the other obtaining “extract liquid” for use in determining the biological response of animals. Further testing of the “extract liquid” is specified in other ASTM standards. The plastic after extraction may also be examined.

1.2 This practice may be used for, but is not limited to the following areas: partial evaluation of raw materials, auditing materials within the manufacturing process, and testing final products. This practice may also be used as a referee method for the measurement of extractables in plastics used in medical devices.

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

1.4 *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:

- D 543 Test Method for Resistance of Plastics to Chemical Reagents²
- D 570 Test Method for Water Absorption of Plastics²
- D 618 Practice for Conditioning Plastics and Electrical Insulating Materials for Testing²
- D 1193 Specification for Reagent Water³
- D 1239 Test Method for Resistance of Plastic Films to Extraction by Chemicals²
- D 1898 Practice for Sampling of Plastics⁴
- E 171 Specification for Standard Atmospheres for Condi-

tioning and Testing Materials⁵

3. Terminology Definitions

3.1 *extraction vehicle*—a liquid specified for use in testing the plastic. Specific extraction vehicles are to be designated by the ASTM standard that references this practice (see Section 7 for a list of standard extraction vehicles).

3.2 *extract liquid*—that liquid which is tested for biological and chemical/physical response; the end result of this practice.

3.3 *specimen portion*—the unit or units of plastic placed into the extraction vehicle.

3.4 *blank*—the extraction vehicle not containing the specimen under test which is used for comparison with the extract liquid.

4. Summary of Practice

4.1 Standard-size specimens of the plastic, which may closely simulate the intended device depending upon the use, are immersed in definite volumes of selected liquids (extraction vehicles) for the time and temperature specified.

4.2 A choice is made, based on the end use, of the extraction vehicles (see Section 7) and one of the combinations of time and temperature for the test (see Section 12).

4.3 The resultant test liquids (extract liquids) are kept in glass containers until used for testing. Test liquids for biological testing are kept in sterile glass containers. The test liquids for biological testing should be used within 24 h.

5. Significance and Use

5.1 These extraction procedures are the initial part of several test procedures used in the biocompatibility screening of plastics used in medical devices.

5.2 The limitations of the results obtained from this practice should be recognized. The choice of extraction vehicle, duration of immersion, and temperature of the test is necessarily arbitrary. The specification of these conditions provides a basis for standardization and serves as a guide to investigators wishing to compare the relative resistance of various plastics to extraction vehicles.

5.3 Correlation of test results with the actual performance or serviceability of plastics is necessarily dependent upon the

¹ This practice is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility.

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² Annual Book of ASTM Standards, Vol 08.01.

³ Annual Book of ASTM Standards, Vol 11.01.

⁴ Annual Book of ASTM Standards, Vol 08.02.

⁵ Annual Book of ASTM Standards, Vol 15.09.