Designation: G121 – 18

Standard Practice for Preparation of Contaminated Test Coupons for the Evaluation of Cleaning Agents[1]

This standard is issued under the fixed designation G121; 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 describes the procedure for the preparation of single- and double-sided contaminated test coupons for the evaluation of cleaning agents. It is applicable for the evaluation of cleaning agents proposed for the cleaning of oxygen equipment, pharmaceutical manufacturing equipment, and medical devices (see Test Method G122 and Guide G127). It also is applicable to other systems where contamination is a concern.

1.2 Several classes of contaminants/residues most likely to be found in oxygen equipment, pharmaceutical manufacturing equipment, and medical devices are identified. However, if the user of this practice has identified contaminants not included in these classes, such identified contaminants may be substituted for the preparation of the test coupons if appropriate for this test method.

1.3 Solvent and cleaning agent compatibility with nonmetallic substrates should be verified prior to the preparation of the test coupons. Typical nonmetallic materials utilized in oxygen systems are contained in Guide G63.

1.4 *This practice may involve hazardous materials, operations, and equipment. This practice does not purport to address all of the safety concerns associated with its use. It is the responsibility of whomever uses this practice to consult and establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1193 Specification for Reagent Water

E1235 Test Method for Gravimetric Determination of Nonvolatile Residue (NVR) in Environmentally Controlled Areas for Spacecraft

E3106 Guide for Science-Based and Risk-Based Cleaning Process Development and Validation

F303 Practices for Sampling for Particles in Aerospace Fluids and Components

F312 Test Methods for Microscopical Sizing and Counting Particles from Aerospace Fluids on Membrane Filters

F324 Test Method for Nonvolatile Residue of Volatile Cleaning Solvents Using the Solvent Purity Meter (Withdrawn 1987)[3]

F331 Test Method for Nonvolatile Residue of Solvent Extract from Aerospace Components (Using Flash Evaporator)

F3127 Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices

G63 Guide for Evaluating Nonmetallic Materials for Oxygen Service

G94 Guide for Evaluating Metals for Oxygen Service

G122 Test Method for Evaluating the Effectiveness of Cleaning Agents

G127 Guide for the Selection of Cleaning Agents for Oxygen-Enriched Systems

2.2 *ANSI Standard:*[4]

B46.1 Surface Texture (Surface Roughness, Waviness, and Lay)

3. Terminology

3.1 *Definitions:*

[1] This practice is under the jurisdiction of ASTM Committee G04 on Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres and is the direct responsibility of Subcommittee G04.02 on Recommended Practices.

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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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.1 *blank, n*—the contamination level of the fluid when the test coupon is omitted.

3.1.1.1 *Discussion*—Sometimes referred to as "background" level.

3.1.2 *cleaning agent, n*—an agent used to support the removal of contaminant from equipment surfaces or other critical objects (such as a medical device).

3.1.3 *contaminant (contamination), n*—unwanted molecular, non-volatile residue (NVR), and/or particulate matter that could adversely affect or degrade the operation, life, or reliability of the systems or components upon which they reside.

3.1.3.1 *Discussion*—The contaminant could be a drug substance, an intermediate, a formulated product, a lubricant, a machining oil, a solvent, a cleaning agent, etc. The contaminant may migrate to other surfaces or users may become exposed to the contaminant during the use of equipment.

3.1.4 *contaminate, v*—a process of applying contaminant (non-volatile residue (NVR) and/or particulate matter).

3.1.5 *control coupon (witness coupon), n*—a coupon made from the same material as the test coupons, but in this test method is not coated with the contaminant.

3.1.6 *dirty hold time (DHT), n*—the maximum time interval between equipment use and cleaning.

3.1.7 *molecular contaminant (non-particulate contamination), n*—molecular contaminants that may exist in a gaseous, liquid, or solid state and may be uniformly or non-uniformly distributed.

3.1.7.1 *Discussion*—Molecular contaminants may be found as a solution, an emulsion, or in the form of droplets. Molecular contaminants account for most of what constitutes NVR.

3.1.8 *nonvolatile residue (NVR), n*—a molecular and particulate matter remaining following the filtration and controlled evaporation of a solvent containing contaminants.

3.1.9 *particle (particulate contaminant), n*—a general term used to describe a finely divided solid of organic or inorganic matter with observable length, width, and thickness.

3.1.9.1 *Discussion*—Particulates are usually reported as the amount of contaminant by the population of a specific micrometer size, usually defined by its greatest dimension. See methods described in Test Methods F312, Practices F303, or ARP 598 for particle size and population determination.

3.1.10 *surface roughness, R_a, n*—the arithmetic average deviation of the surface profile from the centerline, normally reported in micrometres.

3.1.11 *test coupon, n*—representative surface that is typically a rectangular piece of a material of construction on which a known amount of a compound is deposited to simulate a process residue.

4. Summary of Practice

4.1 The contaminant under study is applied to either one side or both sides of precleaned test coupons in a defined area. The amount of contaminant on the test coupons is determined by weighing the test coupons before and after application. The amount of contaminant applied should be controlled and the variation in weight between test coupons minimized. Test coupons should be tested in a manner that simulates the actual cleaning conditions for the product, equipment, or system. Coupons may be tested immediately to simulate actual cleaning conditions or dried under specified conditions (for example, ambient overnight, 8 h at 104 °C, etc.) prior to testing (for example, for Dirty Hold Time studies). Nonmetallic material test coupons used as inserts, seats, seals, gaskets, etc. may also be prepared by this procedure and are evaluated under actual cleaning conditions.

4.2 Three methods of test coupon preparation are used:
Method A: NVR sample, single side,
Method B: NVR sample, double side, and
Method C: NVR and particulate sample.

5. Significance and Use

5.1 This practice will be suitable to direct the preparation of test coupons with a known amount of contaminant on the surface. A standard test coupon is described and a list of contaminants that have typically been found in oxygen-enriched systems and components is provided.

5.2 These test coupons shall be used in the evaluation of cleaning agents for oxygen-enriched systems and components. This will permit direct comparison within and between test facilities.

5.3 Materials used in other fluid handling systems such as nitrogen, helium, hydrogen, gasoline, etc. may also be prepared for evaluation by this practice.

6. Apparatus

6.1 *Test Coupon*—Panels of the same material of construction and finish as the equipment, product, or system to be cleaned. Other alloys that may be used if the specific alloy is unknown are included in Guide G94. Test coupons should be numbered and in a manner that prevents removal during testing. A specified area of the test coupon may be designated as the test area where the test material is applied. Test coupons may be of different test area dimensions (for example, 5 cm x 5 cm, 10 cm x 10 cm) depending on the test procedure they are used in. An example test coupon configuration is shown in Fig. 1.

NOTE 1—The surface finish of the test coupon should be the same as the part to be cleaned.

6.2 *Balance*—Range to a minimum of 50 g with an 0.1-mg accuracy capable of weighing to ±0.1 mg.

6.3 *Convection Oven*—Capable of maintaining 50 °C ± 5 °C.

6.4 *Spray Applicator*—Capable of applying an even coat of contaminant; that is, an artist's airbrush, perfume atomizer, or a spray device such as that used with window or tile cleaners has been found to apply an even coating of the contaminant in a controlled manner.