Designation: G122 – 20

Standard Test Method for Evaluating the Effectiveness of Cleaning Agents and Processes[1]

This standard is issued under the fixed designation G122; 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.

INTRODUCTION

Many products, systems, and manufacturing equipment require a high degree of cleanliness. For example, many medical devices must be cleaned (the terms clean, cleaned, or cleaning are used intentionally and do not imply disinfect, disinfecting, or disinfected) of residues that may cause problems when they come in contact with patients. Gaseous and liquid oxygen systems must be clean, particularly of hydrocarbons, to avoid the potential hazard of a reaction and subsequent fire or explosion. Pharmaceutical manufacturing equipment must be cleaned to prevent product cross contamination from residues. Cleaning agents need to be identified and selected based on their effectiveness to achieve cleaning of the system, product, or manufacturing equipment. There may also be other considerations, such as chlorinated solvents that have been used to clean systems and equipment that must be free of hydrocarbons and other contaminants and environmental concerns dictate that suitable replacements are needed.

This test method presents a procedure that may be used to evaluate candidate aqueous or non-aqueous cleaning agents for use in cleaning products, systems, or equipment, including medical devices, systems for oxygen service, and drug manufacturing equipment.

1. Scope

1.1 This test method covers a procedure for evaluating the effectiveness and capability of cleaning agents to remove contamination to the desired level. This includes removing drug residues from manufacturing equipment and residues from medical devices (Guide E3106), as well as systems for oxygen service.

1.2 The test coupons/beakers described in this standard provide a representative surface to which contamination can be applied and tested for the ability of a cleaning agent to remove it.

1.3 This test method is a laboratory scale approximation and the actual effectiveness of a particular cleaning agent depends upon the method (temperature, agitation, concentration, etc.) in which it is used and the characteristics of the article being cleaned, such as size, shape, and material. Final evaluation of the cleaning agent should include testing of actual products and cleaning processes.

1.4 *Units*—The values stated in SI units are to be regarded as standard. The values given in parentheses after SI units are provided for information only and are not considered standard.

1.5 *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, health, and environmental practices and determine the safety of each compound on a case-by-case basis.*

1.6 *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

D6317 Test Method for Low Level Determination of Total Carbon, Inorganic Carbon and Organic Carbon in Water

[1] This test method 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 G04.01 on 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.

by Ultraviolet, Persulfate Oxidation, and Membrane Conductivity Detection
D6361/D6361M Guide for Selecting Cleaning Agents and Processes
E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods
E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method
E3106 Guide for Science-Based and Risk-Based Cleaning Process Development and Validation
G93/G93M Guide for Cleanliness Levels and Cleaning Methods for Materials and Equipment Used in Oxygen-Enriched Environments
G121 Practice for Preparation of Contaminated Test Coupons for the Evaluation of Cleaning Agents
G127 Guide for the Selection of Cleaning Agents for Oxygen-Enriched Systems

3. Terminology

3.1 *Definitions:*

3.1.1 *cleanability, n*—relative difficulty for cleaning a piece of equipment, product, or device.

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

3.1.3 *cleaning effectiveness factor (CEF), n*—the fraction of contaminant removed, or remaining, from an initially contaminated test coupon and determined by gravimetric or other analytical techniques (for example, Total Organic Carbon analysis, etc.).

3.1.4 *residual contamination,* R_C, *n*—the absolute mass of contaminant remaining after the cleaning process and expressed in micrograms per square centimetre of area or optionally as milligrams per square foot.

3.1.5 *surface roughness,* R_A, *n*—the arithmetic average deviation of the surface profile from the centerline, normally reported in micrometers or micro inches.

3.1.6 *test beaker, n*—a variant of a test coupon in that the configuration is similar to a laboratory beaker and the process residue under study is deposited on the inner walls or bottom.

3.1.7 *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.

3.1.8 *visual inspection, n*— process of using the human eye, alone or in conjunction with various aids, as the sensing mechanism from which judgments may be made about the condition of the surface to be inspected.

4. Summary of Test Methods

4.1 These test methods provide quantitative results as to the ability of a specific cleaning agent/process for removing selected contaminants from standard coupons. The coupons used for testing are prepared in accordance with Practice G121. To achieve results and data of the highest relevance, the method should be a close model of the cleaning system used that can approximate the conditions (for example, temperature, cleaning agent concentration, agitation, etc.) found during actual cleaning as much as possible. Cleaning may be performed using a cleaning tank with or without ultrasonic agitation, elevated temperature, or other cleaning enhancement features and may depend on the manufacturer's instructions. Cleaning methods may include Immersion models, Cascading Flow models, Clean-In-Place (CIP) models, etc. The effectiveness of the cleaning process is represented as CEF, the cleaning effectiveness factor, the fraction of the contaminant removed as determined by gravimetric or other quantitative techniques. A control coupon is used to account for any corrosion or material removal effects due to the cleaning agent/process, or to account for the normal Loss on Drying due to the contaminant's water or volatile content, unless this has been tested for previously.

5. Significance and Use

5.1 The purpose of these test methods is to define a procedure for evaluating the capability and effectiveness of cleaning agents to remove residues of a compound/product from surrogate surfaces (that is, coupons or beakers) of Materials of Construction. This test method also provides a procedure for determining the compatibility of cleaning agents with the Material of Construction prior to starting tests. Based on the outcome of the testing, suitable cleaning agents may be selected for further cleaning process development (see Guide D6361/D6361M).

5.2 The potential critical cleaning parameters related to the cleaning agent(s) under study may also be examined using these tests. Potentially critical cleaning parameters include cleaning agent concentration, temperature, time, pH, foaming, type and strength of ultrasonic energy or agitation (if used), and others. These parameters may be varied (for example, using Design of Experiments) to determine their potential optimal settings for actual use.

6. Apparatus

6.1 *Materials:*

6.1.1 *Test Coupon/Beaker,* prepared in accordance with Practice G121.

6.1.2 *Control Coupon/Beaker*—This is uncontaminated and is subjected to the identical cleaning procedure as the contaminated coupons and serves to evaluate corrosion and erosion of the test coupons.

6.1.3 *Cleaning Agent,* prepared according to the manufacturer's instructions. If the Cleaning Agent is used after dilution with water, Specification D1193 Type I to IV water shall be used for preparing aqueous solutions or prepared with water of the purity used in the actual cleaning.

6.2 *Equipment:*

6.2.1 *Cleaning Tank,* of sufficient size to conduct a number of evaluations simultaneously. Testing is enhanced by having automatic temperature and time controls. A cleaning tank with ultrasonics may be used.

6.2.2 *Balance,* accuracy to 0.1 mg. However, 0.01 mg accuracy is desirable to detect contamination levels of 10 mg/m^2 (1 mg/ft^2) or less.