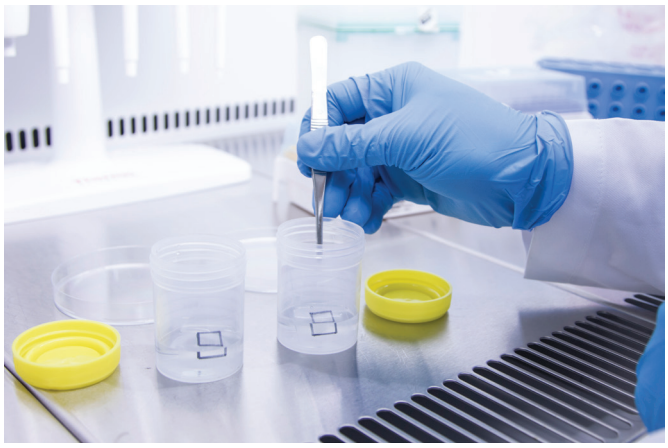
Suspension Test And Carrier Test For Disinfectants According To European Norms

Suspension and carrier tests are two significant test methods listed in EN 14885:2015 to determine if a disinfectant is effective.



A few weeks ago, we explained EN 14885:2015 and why it is particularly important for European manufacturers of disinfectants. Today, we will try to compare two significant test methods listed in the norm and how they are carried out in laboratories to determine if a disinfectant is effective or not. The standard European method of disinfectant validation is comprised of 3 phases and they are determined by the type of test carried out. The methods used come progressively closer to simulate actual environments with each successive phase.

Phase 1: Basic suspension tests

Suspension tests as the name suggests, measure the effectiveness of a disinfectant in inactivating specified test microorganisms within a given contact time in a suspension. There are two basic suspension tests in the European standard; EN 1040:2005 (Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics) and EN 1275:2005 (Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics).

In a suspension test, the test product (disinfectant being tested) is added directly to the test microorganisms in a suspension. Sterile neutralizer is added immediately after the claimed contact time to stop the effects of the disinfectant and a sample of the mixture is poured into a pour plate and incubated. The number of surviving bacteria is counted and compared against the original culture size. No interfering substances are added into the suspension in this phase as the sole aim of this test is to determine the direct effect the test product has on the test microorganisms.

Basic suspension tests are typically performed by researchers during the development stage of a disinfectant to determine if the active ingredients in the disinfectant have antimicrobial properties. The result from phase 1 test cannot be used for efficacy claims as the test does not reflect the effectiveness of the product in actual environments. But, an encouraging result may very well pave the way forward for the manufacturer.

Viroxy Sdn. Bhd. (Co. No. 119 3371-A)
6th Floor · Menara RKT · 36 Jalan Raja Abdullah · 50300 Kuala Lumpur · Malaysia
Phone: +60 (0)3 2776 4875 · Fax: +60 (0)3 2776 4876 · info.kl@viroxylabs.com

Phase 2: Quantitative suspension tests and carrier tests

Phase 2 is divided into 2 steps; Phase 2, Step 1 which refers to quantitative suspension tests and Phase 2, Step 2 which refers to carrier tests to simulate practical usage conditions.

Phase 2: Step 1

Examples of quantitative suspension tests in the European standard are EN 13727:2012 (Quantitative suspension test for the evaluation of bactericidal activity in the medical area), EN 13624:2013 (Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area) and EN 14348 (Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants).

The suspension tests here are similar to basic suspension tests but with one major difference. In phase 2, suspension tests must be conducted to simulate actual medical conditions. This means that the suspension must also contain interfering substances prior to the addition of the disinfectant. In order to test if a disinfectant is effective in clean conditions, the suspension is mixed with bovine albumin which is a type of protein derived from cows as the interfering substance, for example. To test if the product is effective in dirty conditions, the suspension is mixed with bovine albumin and sheep blood. This as you can see, is resemblant of an actual medical environment where these types of contaminants are typically present.

Phase 2: Step 2

Examples of carrier tests in the European standard are EN 14561:2006 (Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area), EN 14562:2006 (Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area) and EN 14563 (Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area).

In a carrier test, the test microorganism is mixed with bovine albumin (for clean conditions) and sheep blood (for dirty conditions) and applied onto a 1cm2 space of glass slide or metal disk for non-porous surface and wood for porous surface. These materials act as the actual surface (or carrier of microorganisms). The carrier is then left to air-dry to mimic actual medical surfaces before the disinfectant is applied for the duration of the claimed contact time. It is then submerged into a neutralizer solution to prevent continued disinfection. The assumption here is that the microorganisms are suspended in the neutralizer upon immersion. A sample of the neutralizer solution is then acquired, plated and incubated. The number of test microorganisms recovered is compared to the number of microorganisms recovered from the control sample (where test microorganisms are exposed to water instead of disinfectant) to determine if the disinfectant is able to reduce relevant test microorganisms to an acceptable level as outlined in the norms.

At this stage, it is sometimes revealed that the level of concentration required to pass the suspension test must be increased in order to pass the carrier test. Surface tests also involve the use of mechanical action to simulate the application of a cloth or a mop. As mechanical action can be quite difficult to replicate, some recommend this to be examined in phase 3 field test.

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Phase 2 tests provide a defined set of laboratory conditions that simulate actual conditions such as contact time, temperature, soiling, etc. for the evaluation of disinfectants. However, there are differences between conditions manufactured in a laboratory and actual environments. Even so, positive results from appropriate phase 2 tests are usually sufficient to demonstrate efficacy for commercial and product authorisation purposes.

Phase 3: Field test

Phase 3 tests are usually undertaken when the test product or disinfectant involves a new technology which lacks historical data to support claims of efficacy or lacks suitable standardised laboratory methods.

The pros and cons of suspension test and carrier test

	Pros	Cons
Suspension test	• Test product has better contact with the microorganisms in a suspended state • Test is easier to conduct • Microorganism count is maintained throughout test	• Not representative of the actual environment as test microorganisms are not adhered to a specific surface or material • Small dilution errors made during the preparation of disinfectant solution can have a big impact on the outcome of the test • Disinfectants with high viscosity may not be distributed evenly in the test suspension
Carrier test	• Test better represents actual conditions compared to suspension test • Microorganisms are adhered to a carrier as they are in actual conditions	• Death / loss of microorganisms during the drying process makes it difficult to control the number of microorganisms retrieved • Surfaces are not truly identical and can pose a challenge in reproducing the same result • Slightly more tedious than suspension test

Viroxy has a team of highly qualified microbiologists who are experienced in conducting suspension tests and carrier tests. Call us today at +60 (0)3 2776 4875 to discuss your disinfectant efficacy testing requirements.

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