

Sterility Test

As a global leader in sterility testing, we offer you an unparalleled experience in generating protocols and performing method suitability testing (inhibition/suppression) to validate testing processes based on product-specific formulations, lot sizes, and fill volumes. Reliable sterility testing and development or validation of product-specific methods are key processes in drug development. Test records can be established for in-process and final product testing of pharmaceuticals and formulations.



About Sterility Test

Sterility testing is used to confirm that sterile products do not contain live microorganisms before release and administration. Due to the importance of sterility testing methods for medical devices, pharmaceuticals, formulations, tissue materials, and other products that claim to be sterile or free of live microorganisms, it is important that sterility testing methods be as accurate as possible.

Sterility Testing Methods

Sterility testing is required to ensure the absence of visibly contaminating microorganisms in pharmaceutical preparations, and the pharmacopeial method for testing the sterility of pharmaceutical products requires that samples be cultured in two separate media. In aseptic testing, the testers use two different media to promote

the growth of residual anaerobic, aerobic and fungal bacteria. Samples need to be incubated for 14 days prior to the assay. The presence of turbidity in the media indicates that microbial growth may be present and must be investigated. In general, we offer direct inoculation and membrane filtration methods.

- **Direct Inoculation**

Specimens are inoculated directly into both media to detect both aerobic and anaerobic microorganisms. After inoculation, both media are incubated for 14 days. Intermittent observations and a final observation at the end of the test period are performed to detect evidence of microbial contamination.

- **Membrane Filtration**

A sterile, closed device allows simultaneous filtration of equal volumes of test samples through two membrane filters. Samples are incubated in both types of media for 14 days to facilitate the detection of aerobic and anaerobic microorganisms.

Bacteriostatic/Fungal Inhibition Test

In combination with aseptic testing, bacterial inhibition testing is performed to assess whether the test article inhibits the growth of microorganisms. The performance of the B/F test is necessary to verify the aseptic results and confirm the absence of antimicrobial properties in the test article that would inhibit the detection of microorganisms during aseptic testing.

Vaporized Hydrogen Peroxide (VHP) Invasion Test

The vaporized hydrogen peroxide (VHP) entry test is performed in a VHP decontaminated isolator. This assay evaluates whether VHP has visibly entered the test article container, which may affect the validity of the results.

In addition to the above services, we offer a simplified validation service that makes implementation easier than ever. This allows you to get your product to the patients who need it faster.

Why do Sterility Tests Need to be Performed for 14 Days?

The sterility test is 14 days, allowing for an appropriate incubation period to detect slower growing microorganisms. While many bacterial and fungal organisms can be detected in a short incubation period, some microorganisms require a longer incubation period to proliferate.

Source: <https://www.formulationbio.com/sterility-test.html>