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Perspective

Microbiology Screening in Sterile Pharmaceuticals and Applications for Microbiological Sterility Tests

Kolos Jolanta*

Department of Pharmaceutical Genetics and Microbiology, Poznan University of Medical Sciences, Grunwaldzka, Poland

DESCRIPTION

Sterility testing is a GMP microbiological testing requirement that ensures sterile products are free of live microorganisms before being released and administered to patients. Membrane filtering, Direct Transfer (Product Immersion), and Product Flush are the three methods of sterility testing.

Membrane filtration method for sterility testing for pharmaceutical products, the membrane filtration sterility test is preferred for devices that contain a preservative and are bacteriostatic and fungistatic using the direct transfer method, this test is appropriate. Microorganisms are supposed to accumulate on the surface of a sub-micron pore size filter when using membrane filtration. This filter is divided and sent to the proper media. Fluid Thioglycollate Medium (FTM) and Soybean Casein Digest Medium (SCDM) were used as the test media (SCDM). The ability of FTM to sustain the growth of both anaerobic and aerobic bacteria is a key factor in its selection. SCDM was chosen because it can support a diverse spectrum of aerobic bacteria and fungi (i.e., yeasts) and 14 days is the incubation period.

Direct transfer sterility testing, this method is the method of choice for medical devices because the device is in direct contact with test media throughout the incubation period. Microorganisms that survive sterilisation and remain in or on a product have an excellent environment in which to grow and proliferate. This is particularly true for bacteria that have been harmed by a sub-lethal sterilising technique. Biological repair processes exist in all microbes, allowing them to take advantage of development conditions. These injured bacteria benefit from the direct transfer procedure. Test fluid should be poured over the entire product. The entire product should be immersed in test fluid. With large devices, patient contact areas should be immersed. Due to the size and shape of test samples, Nova recognises that necessary changes are required.

Product flush sterility testing, the product flush sterility test is used for reserved for products that hollow tubes, such as transfusion and infusion assemblies, where immersion is not possible and the fluid channel is identified as sterile. This method is easy to implement and just modification a change to the FTM media for small lumen devices. The products are flushed with fluid, and the elevate the membrane filtered before being injected into the FTM and SCDM.

Interpretation of sterility test results, the media is examined for growth during the incubation period. Against a light source, the media should be clear and transparent Turbid (cloudy) areas in the media are indicative of microbial growth. Once growth has been found, the suspect vessels analysed to ensure that the turbidity is caused by microorganisms and not due to disintegration of the sample. Because of particle shedding or chemical reactions with the media, turbidity might occur in some samples. Sometimes samples produce turbidity because of particulate shedding or chemical reactions with the media. Samples that render the media turbid are transferred on day 14 of the test, samples that make the media turbid are transferred and incubated for four days. Growth positive samples will need to be processed further. Sterility testing of pharmaceutical articles is required during the sterilization validation process as well as for routine release testing. USP requirements employ sterility testing as an official test to determine suitability of a lot. This approach entails passing an amount of drug product through two canisters, each of which has a microorganism-retention filter. This is followed by a rinse to ensure no drug product remains on the filter, as that can potentially inhibit the growth of microorganisms.

Correspondence to: Kolos Jolanta. Department of Pharmaceutical Genetics and Microbiology, Poznan University of Medical Sciences, Grunwaldzka, Poland, Email: jolanta.kolo.phs@gmail.com

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