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Sterility Testing of Products (Solids, Liquids, Ophthalmic and Other Sterile Products) According to IP, BP and USP

Precautions to avoid microbial contamination, Verify the Sterility of the Product Being Examined, Direct inoculation of culture medium

The test is used on drugs, preparations, or products that must be sterile according to the Pharmacopoeia. An acceptable result, on the other hand, just shows that no contaminating microorganisms were discovered in the sample analyzed under the test parameters.

Precautions to avoid microbial contamination

The sterility test is performed under aseptic circumstances. To attain such circumstances, the test environment must be tailored to the manner in which the sterility test is carried out. In terms of microorganisms exposed in the test, the steps made to prevent contamination do not affect them. The working conditions under which the tests are carried out are checked on a regular basis by suitable sampling of the working area and the implementation of relevant controls.

Verify the Sterility of the Product Being Examined

A membrane filtration test can be performed or the culture medium can be directly inoculated with the product to be tested. Positive controls are also provided. Filtrations by membrane are employed for products whose nature allows it, e.g., In the absence of antibacterial properties in test conditions, water-soluble aqueous preparations, alcohol-based and oil-based solutions, and solutions miscible in or soluble in water or oil are not suitable as antibacterial agents.

The procedure described below presupposes the usage of membranes with a diameter of around 50 mm. If various diameter filters are employed, the quantities of the dilutions and washings must be adjusted proportionately. The filtration equipment and membrane are sterilized using acceptable methods. The apparatus may either be constructed so that the solution to be investigated may be placed into the apparatus and then filtered under aseptic conditions, or it may be designed so that the membrane can be removed for transfer to the medium aseptically, or it may be used for

Aqueous solutions

Pour a small quantity of sterile diluent into the device and filter, such as a pH 6.9 to 7.3 neutral protein peptone solution. In the case of antibiotics, for example, the diluent may contain appropriate neutralizing and/or inactivating chemicals.

Using the sterile diluent used in the method appropriateness test, dilute the contents of the container or containers, and then transfer them to a membrane or membranes, not less than the quantity of the diluent used in the method appropriateness test. After filtering, discard the filtrate. The membrane must be washed three times with the specified volume of sterile diluent used in the technique appropriateness test each time if the product has antibacterial properties. Wash filters no more than five times in 100 ml per cycle, even if the method appropriateness analysis has established that such a cycle does not destroy all antimicrobial activity. In the case of whole membranes, they can be transferred to the culture medium or, if divided into two equal sections, one half can be transferred to each of two acceptable media. Use the same amount of each medium as you used in the technique appropriateness test.

The medium can also be transferred onto the apparatus' membrane. Ensure that the medium is incubated for at least 14 days.

Quantity per container	Unless otherwise justified and approved, a minimum quantity of each media must be employed.
<i>Liquids</i>	
Less than 1ml.	Each container's entire contents
1-40ml	Half of the contents of each container, but no less than 1 millilitre.

(X)

More than 100ml Antibiotic liquids	1ml
Ointments, creams, lotions, and preparations in which suspension or emulsification is not possible	To achieve a minimum dosage of 200 mg, use the contents of each container.
<i>Solids</i> Less than 50mg More than 50mg or 50mg but no more than 300mg 300mg – 5g More than 5g	Each container's entire contents half the contents of each bottle, but no less than 50 milligrams. 150mg. 500mg.

Soluble solids

The amount specified in Table 2 of product dissolved in a suitable solvent, such as the solvent provided with the preparation, water for injection, sodium chloride (9 g/l) TS, or peptone (1 g/l) TS1 should not be less than that prescribed, and the test should be carried out as described here for aqueous solutions using the appropriate membrane.

Oils and oily solutions

To use each media, you must use at least as much product as specified in Table 2. Oils and oily solutions with sufficiently low viscosity can be filtered via a dry membrane without dilution. Viscous oils can be diluted as needed with an appropriate sterile diluent, such as isopropyl myristate R, which has been demonstrated not to have antibacterial action in the test circumstances.

You can gradually increase the suction or pressure of the filter by letting the oil pass through by its own weight before filtering. An emulsifying agent at a concentration of 10 g/l of polysorbate 80 proved adequate in the method suitability test. After washing the membrane with 100 ml of a sterile solution, such as peptone (1 g/l) TS1, apply the same sterile solution to the plate. Alternatively, you can transfer membranes to a culture medium or media, or vice versa, at the same temperatures and periods described above for aqueous solutions.

Ointments and creams

The amounts of the product for each media should not be less than those specified in the table. Ointments with a fatty basis and water-in-oil emulsions can be diluted to 1% in isopropyl myristate R as described above, by heating to no more than 40 °C if necessary. Occasionally, heating to a temperature of no higher than 44 °C is necessary. Filter as soon as possible and proceed with the oils and greasy solutions as mentioned above.

Direct inoculation of culture medium

concentrated culture medium that has been prepared to allow for eventual dilution.

Ointments and creams

In a sterile diluent, such as 1 gram/l of peptone (TS1), emulsify the specified emulsifying agent together with the specified diluent. Dilute the product in an emulsifying agent-free medium.

Incubate the infected medium for a minimum of 14 days. During the incubation phase, check on the cultures many times. Every day, carefully shake cultures containing greasy ingredients. However, when using fluid thioglycollate medium to identify anaerobic microbes, keep shaking or mixing to a minimum to preserve anaerobic conditions.



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