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Diploma in Pharmacy 1st Year
Pharmaceutics
Experiment
To demonstrate the sterility testingof sterile injections as per the monographs.

Aim:

To demonstrate the sterility testing of sterile injections as per the monographs.

Reference :

‘ Dr. Gupta G.D , Dr. Sharma Shailish , Dr. Sharma Neelam’ “Practical Manual of Pharmaceutics” Published by Nirali Prakashan, Page no 187 – 190

Apparatus and Materials Required :

Membrane filters having pore size not greater than 0.45um and diameter 47mm. soybean-casein digest medium (100ml), incubator, thioglycolate medium (100ml), inoculated medium, soybean-casein digest medium and sterile injection

Theory :

Sterility test is a confirmatory test for sterilisation process. Parenteral preparations such as injectables, ophthalmic products, and absorbent cotton are tested by this test, which is performed aseptically to avoid product contamination during the test.

Principle

Sterility test works on the principle that on supplying microorganisms with nutrient medium and incubating them under favourable temperature, they start growing and multiplying, and theu presence can be detected by the appearance of turbidity in the clear medium

Preparation of Culture Media

The culture media used for sterility testing should stimulate the growth of various acrobic and anaerobic microorganisms such as bacteria and fungi. Two types of culture media that can be used are

1) **Fluid Thioglycolate Medium:** This medium supports anaerobic as well as aerobic bacterial growth.

Table 9. enlists the ingredients and their quantities used for preparing this medium:

Table 9: Composition of Fluid Thioglycolate Medium

Ingredients	Quantity (for 100ml)
L-cysteine	0.5gm
Sodium chloride (NaCl)	2.5gm
Dextrose	5.5gm
Agar	0.75gm
Yeast extract	5.0gm
Pancreatic digest of casein	15.0gm
Sodium thioglycolate	0.5gm
Resazurin (0.1% fresh solution)jslktqfju	1.0ml
Distilled water (q.s.)vklqr ty	1000ml

2) **Soybean-Casein Digest Medium:** This medium supports aerobic bacterial growth and fungal growth. Table 10 enlists the ingredients and their quantities used for preparing this medium.

Table 10: Composition of Soybean-Casein Digest Medium

Ingredients	Quantity(for 1000mlo
Pancreatic digest of casein	17.0gm
Peptic digest of soybean meal	3.0m
Sodium chloride	5.0m
Dibasic potassium phosphate(K_2HPO_4)	2.5m
Dextrose	2.5m
Distilled water (q.s.)	1000ml

Sampling (Selection of the Size of Samples)

The sample itself and its number should be procured from the given batch of sterile product. The material should be thoroughly mixed if the sample is to be obtained from the bulk. The sample is withdrawn randomly from the batch of final containers.

Procedure

Sterility testing is performed by the following methods:

1) **Membrane Filtration Method :** This method is used when the test substance is:
   i. An oily preparation,
   ii. An ointment that can be placed in the solution,
   iii. A soluble powder or a liquid with antimicrobial properties,
   iv. A solid with no antimicrobial properties and not readily soluble in the culture media, and
   v. A liquid product whose volume in a container is 100ml or more.

Procedure: Sterility test utilises membrane filters having pore size not greater than 0.45pm and diameter 47mm. These filters should retain microbes. The filtration system and the membrane should be sterilised and the substances are membrane filtered under aseptic conditions The membrane is washed thrice each with 100ml of sterile solvent if the substances have antimicrobial properties. Then the membrane is aseptically cut into two equal halves. One half is immersed in soybean casein digest medium (100ml) and incubated at 20-25°C. The other half is immersed in fluid thioglycolate medium (100ml) and incubated at 30-35°C for a week.

2) Direct Inoculation Method: The test substance to be used in each culture medium is directly transferred or inoculated into the culture media aseptically, This inoculated liquid is mixed with the medium. If the test substance contains antimicrobial properties, it is neutralised with the

addition of inactivating substances (e.g. penicillinase in case of penicillin) to the medium. The inoculated medium is incubated at 20-25°C with soybean-casein digest medium and at 30-35°C with fluid thioglycollate medium for a week.

3) **Positive Control Test :** This test is performed to make sure that the culture media prepared and the environment conditions maintained during the test period support the microbial growth. The culture media is streaked under aseptic conditions with the causative test microorganism and then the method discussed above is adopted On completion of the test growth or multiplication in the microbial load should be observed.
4) **Negative Control Test :** This test is performed to make sure that the proper sterile conditions have been maintained in the test area. The sterilised culture media is exposed to the test area and incubated. At the end of the study, there should not be any growth in the culture media, thereby proving the sterility and absence of microorganisms in the working area, an example is the laminar airflow unit.

Observation and Interpretation

At intervals during the incubation period and on its completion, the media are examined for the presence of growth of microorganisms. If the material under test makes the medium turbid, detection of microbial growth by visual inspection becomes difficult. Two weeks after the beginning of incubation, Iml portions of each medium are transferred to fresh vessels containing the same medium. Then, the original and transfer vessels are incubated for 4 days. If no microbial growth occurs, the preparation is considered to pass the sterility test, while if microbial growth is observed, the preparation fails the test. The sterility test is not repeated unless it can be proved that the test was invalid for reasons unrelated to the preparation being tested

If the test is declared to be invalid, it is repeated using the same number of units in the original test. If no microbial growth is observed in the repeat test, the paration passes the sterility test, while if microbial growth is observed which men confirmed microscopically, the preparation fails the test.

Result :

The sterility testing of sterile injections as per the monographs was studied.

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