

# Sterility Testing / Test for sterility

Page No.            **MIRAJ**

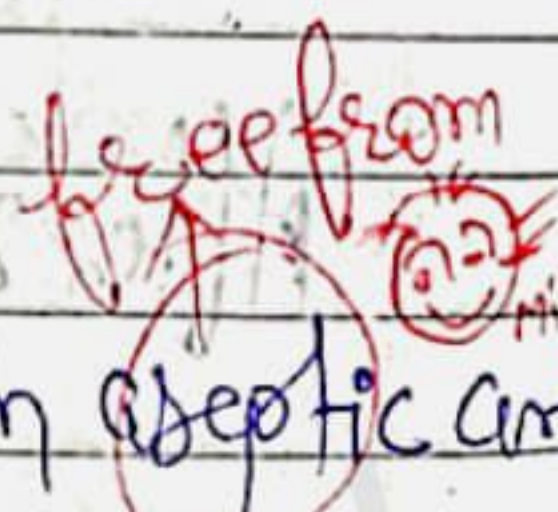
⇒ Test for sterility is the qualitative test to be performed on product who gone through sterilization process. To ensure that product are actually sterile & free from Microorg. [DEPTH OF BIOLOGY]

⇒ Pharmaceutical product need to be sterilise and Ophthalmic preparations, Injection, Implants, Syringes, bandages, dressing, Needle, Surgical instrument etc.

⇒ Sterility testing is performed on Pharmacopoeia recommended number of sample & not on entire Batch. [DEPTH OF BIOLOGY]

⇒ It is the process of validating sterilization step while making sterile preparation.

⇒ Sterility testing must be carried out in aseptic area to avoid accidental contamination of the product during the test. [DEPTH OF BIOLOGY]

free from 

# When to perform Sterility Testing

Formulation of product in aseptic conditions.



Sealing & capping of products in aseptic condition.



Sterilisation of product by suitable process (Physical or Chemical).

[DEPTH OF BIOLOGY]



Sterility testing of recommended sample ~~from~~ sterilization batch.



If passes the sterility test then product of that batch is labelled as sterile products.

Sterility Testing  $\Rightarrow$  Principle.

[DEPTH OF BIOLOGY]

The test of sterility is based upon the principle

that if the preparation after sterilization

is not sterile (presence of viable microorg.) & if that preparation

in adequate quantity placed in a medium which provides

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nutritive Material & water & kept at a favourable Temp.

The microorg. will grow & their presence can be indicated

by a turbidity in the originally clear medium.

⇒ If the turbidity is not observed after incubation period it clearly indicates that product are actually sterile.

⇒ The probability of detecting viable microorg. in the test for sterility increases with the number of sample used being tested.

⇒ Presence of species like bacteria & fungi are to be examined in this test.

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## # Number of items recommended to be tested in the batch (as per IP)

Preparations	Number of Item in the batch.	Min. no. of items are recommended to be tested.
Injectible Preparation	1 to 100	10% or 4 containers (whichever is greater)
	101 to 500	10 containers
	501 & more	20% or 20 containers (whichever is less).

[DEPTH OF BIOLOGY]

2. Ophthalmic & other Non-Injectable Preparation. 1 to 200 5% or 2 Containers [DEPTH OF BIOLOGY]

201 & more 10 Containers

3. Surgical Dressing [DEPTH OF BIOLOGY] 1 to 100 packages 10% or 4 Packages

101 to 500 Packages 10 packages

501 & More Packages 20 packages

4. Ophthalmic & other Non-Injectable Preparations. 1 to 3 container Each container

4 to 50 containers 4 containers

51 & More Containers 10 containers

# Method for Sterility Testing ⇒ [DEPTH OF BIOLOGY]

Sterility can be carried out by using following Methods ⇒

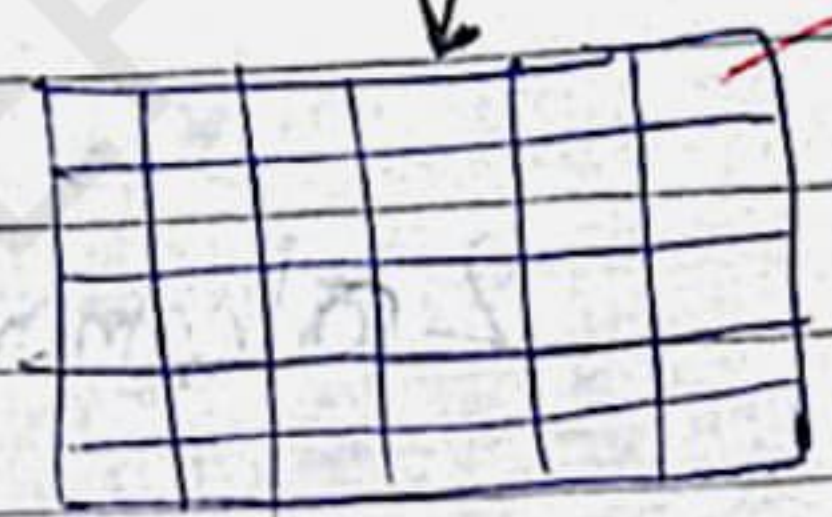
① Method A ⇒ Membrane filtration. (Pharmaceutical Engineering)

② Method B ⇒ Direct Inoculation.

① Memb. filtration ⇒

Afterster. ko pdto k v  
skta h

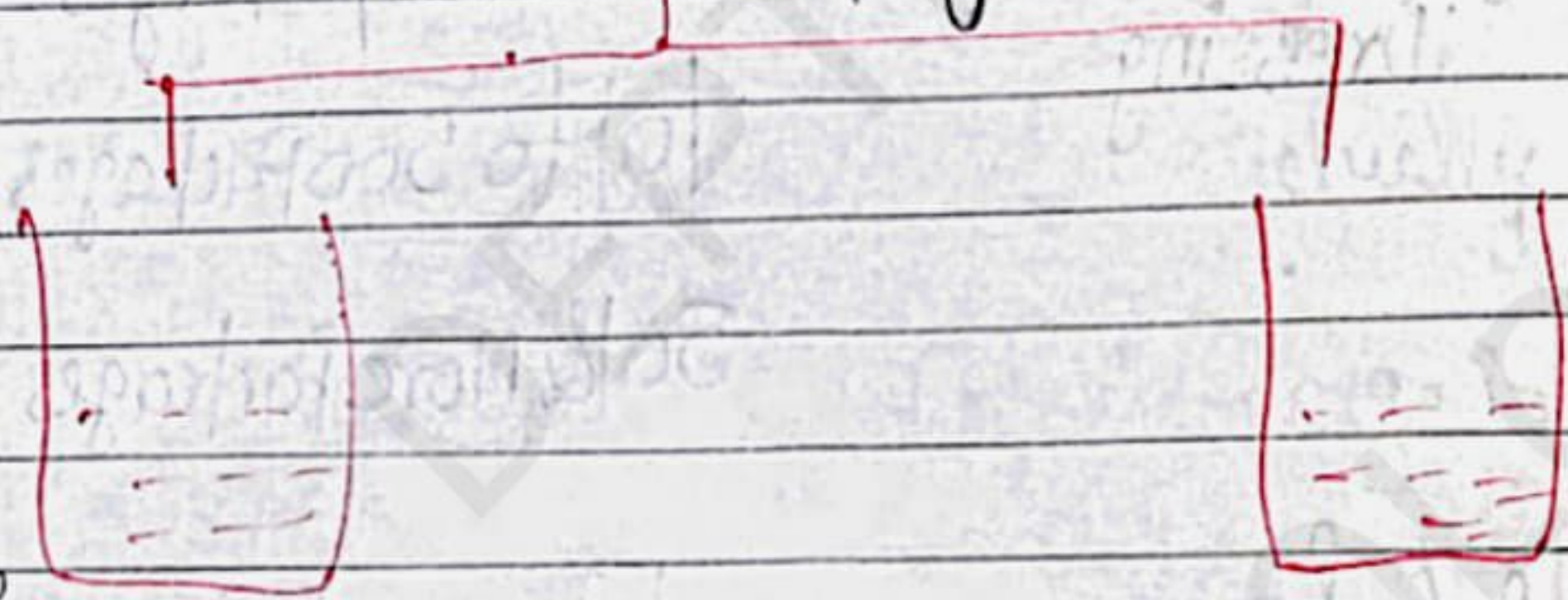
pores → size 0.45 μm



Memb. filter.

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↓  
Now Probs filter



Thioglycolate  
Medium

Soyabean Casein  
Medium

↓  
Incubate at 30-35°C  
for atleast 7 days

↓  
20-26°C  
14 days

↳ see → turbidity show ⇒ Test fail.

↳ see ⇒ Pass

[DEPTH OF BIOLOGY]

② Direct Inoculation ⇒

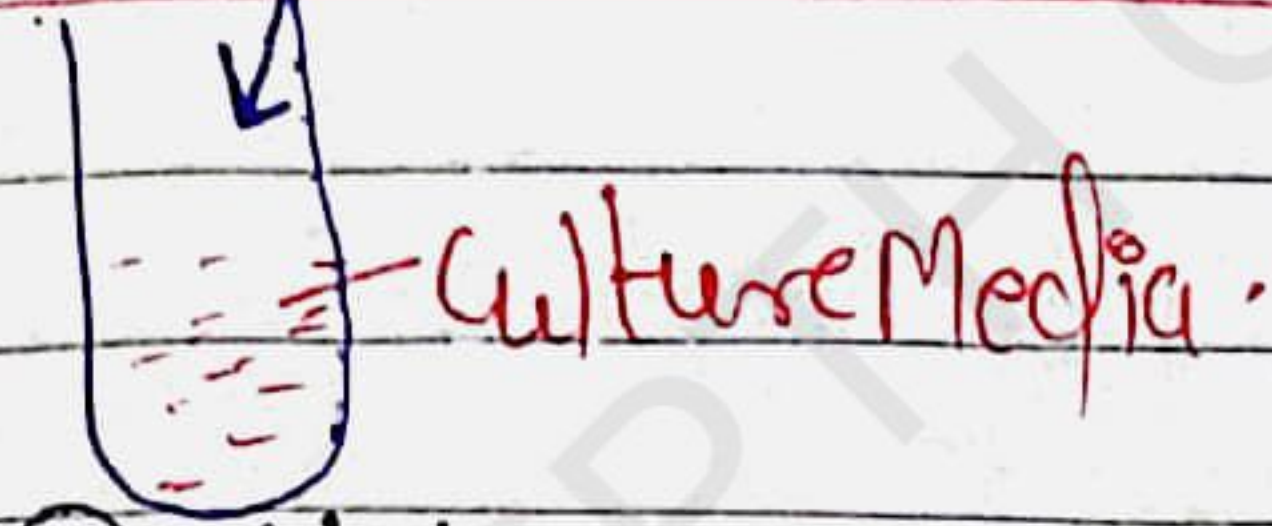
Requirement ⇒ Test Tube, Test Tube stand

↑  
Containing Culture Media.

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# Test to Sample को

Mix करनी है

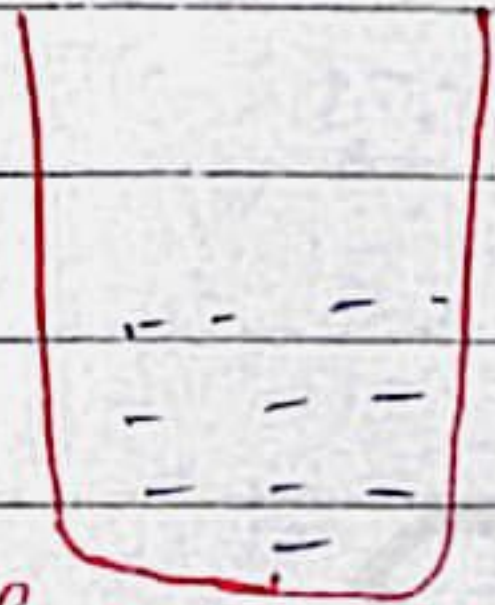


Test tube

[DEPTH OF BIOLOGY]



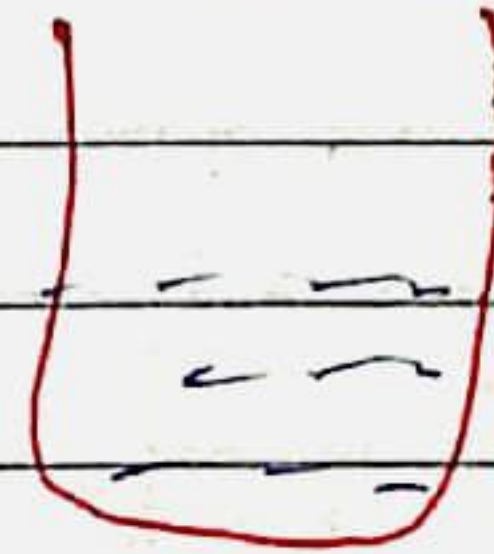
[DEPTH OF BIOLOGY]



Thioglycolate Med.

30-35°C

7 days.



Soyabean Med.

20-25°C

14 days

Result ⇒ Turbidity → ✓ ⇒ Fail

Turbidity → X ⇒ Pass.

[DEPTH OF BIOLOGY]