Evaluation of Microbial Stability of formulati

Preservatives की तीव्रता का पता लगाना ⇒ Preservative efficacy Test].

→ This test is apply to the formulated medicine in its final
जो market में जाने वाली है।
Container to determine wether it is protected against microbial spoilage. [DEPTH OF BIOLOGY]

⇒ It is used to check stability of Multiple dose, such as Parentral, oral, Nasal, Topical & opthalamic products Made with aq. Bases or Vehicle. [DEPTH OF BIOLOGY]

→ It is used to check the effectivness of antimicrobial preservatives. [DEPTH OF BIOLOGY]

These pharmaceutical formulation also evaluated at time to time. (once evaluated Under 6 Month).

— The test & Standard apply only to the product in the original, Unopened Container in which it is supplied by Manufacture. → Means packed / New brand / Not sample container.

Medium Used →

For the Initial Cultivation of test microorg. use Soyabean Casein digest Agar Medium.

Choice of test Microorg. & Inoculum Prepration

The Intension is to use microorg. which are likely to arise in the raw material used in the product & which occurs in the manufacturing environment & represent a Particular Health Hazard, if they grow in the products.

— The test Microorg. used for Preservative efficacy test are → पिछे पिछे पिछे (Sky low Space)

- Staphylococcus aureus ATCC 6538 ;
- Pseudomonas Aeruginosa ATCC 9027,
- E-Coli ATCC 8739,
- Candida Albicans ATCC 10231
- Aspergillus Brasiliencis ATCC 16404.

⇒ Fresh Stock Culture of each test microorg. is subcultured on the surface of Soyabean Casiem digest Agar Medium

⇒ Incubate the Bacterial Culture at 30-35°C for 18-24 Hours.

⇒ Using Sterile Saline Solution, Harvest the bacteria & dilute suitably with Sterile Saline Soln. to bring the count to about 1×10^8 CFU/ml. → Colony forming Unit.

PROCEDURE ⇒

Inoculate each original product Container with one of the Standerised Microbial Suspension Using a ratio equivalent to 0.1ml of Inoculum Suspension to 2ml. of Product & Mix.

→ Final Conc. should be $1 \times 10^5 - 1 \times 10^6$ microbes per ml of Product.

— Determine the Number of Viable Microorg. by the Plate Count Method & Calculated the Initial Conc. of microbes per ml.

— Incubate the Inoculate Containers or tube at room temp.

— Determine the Viable Count by the plate Count method at 7, 14 & 28 days subsequent to Inoculation.

— Calculation the Percentage of reduction in C.F.U per ml for each organism at the stated test Intervals & express the Change in terms of percentage of Initial Conc.

CFU [Colony forming Unit].

Interpretation of Result

⇒ For parentral, opthalmic, Sterile Nasal, otic preprations Conc. of Viable Bacteria is Not More then 10% of Initial Construction at 7 days & Not More then 0.1% of Initial Conc. at 14 days and there is further decrease in count at 28 days.

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⟹ For topical prepration ⟹ [DEPTH OF BIOLOGY]

Conc. of Viable bacteria is Not more then 1% of Initial Conc. at 14 days & there is further decrease in Count at 28 days. [DEPTH OF BIOLOGY]

For oral prepration ⟹

Not more then 10% of the Initial Conc. at 14 days & further decrease.