

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10299

6505-390-2218 (P. D. No. 2)

4.3.4 Total bacteria count. The bacteria content shall be determined as follows:

Reagent.

1. Plate Count Agar. Prepare according to label directions (Trypton Glucose Extract Agar may also be used).

Procedure. Place 4 ml of purified water in a 18 by 140 mm test tube and sterilize by autoclaving for 1 hour at 15 pounds pressure. Incubate the sample of the finished suspension for three (3) days at 37° C. before plating. Remove sample from oven, shake thoroughly and aseptically transfer a 1.0 ml aliquot to 18 by 140 mm test tube containing 4 ml of sterile purified water, using standard serological procedure for rinsing the pipet and mixing the sample. Aseptically pipet 1.0 ml of the diluted sample into a sterile Petri dish and pour about 10 ml of plate count agar (48° - 50° C.) into the plate. Cover and mix the sample by swirling. Allow the agar to gel and then incubate at 37° C. for 40 to 48 hours. Remove the plates and count the number of organisms on each plate.

4.3.5 Mold content. The mold content shall be determined as follows:

Proceed as for the bacteria count (4.3.4), except use Sabouraud's dextrose or maltose agar and incubate at 25° - 30° C. for 5 days.

4.3.6 Defoaming action. The defoaming action shall be determined as follows:

Reagents.

1. Triton X-100
2. F.D. & C. Blue #1 dye.

Procedure. Prepare a 1 percent (w/v) solution of Triton X-100 in purified water. To each liter of this solution add 5 mg of F.D. & C. Blue #1. Clamp a new, clean eight ounce, flint glass jar in a vertical position on a wrist action shaker so that the distance between the center of the shaft and the center of the jar is 5-1/4 inches. Add 100 ml of the Triton X-100 solution to the jar. Shake a sample of the finished suspension thoroughly and withdraw 1.0 cc using a 1.0 cc syringe. Add the 1.0 cc sample directly to the jar, cap the jar, and using the position for maximum stroke, shake the jar for 10 seconds. Determine the collapse time of the foam in seconds. The collapse time is taken when the first portion of foam-free liquid surface can be observed. The presence of the blue dye aids in the detection of the foam-free liquid surface. Repeat the test with a fresh sample and a new clean jar. Average the results to report the defoaming activity.