

Scope

This method covers the determination of the time required for a water-soluble film to break apart (disintegrate) and its subsequent relative dissolution time when held stationary in a plastic fixture. The technical department (QA, R & D, and PCT) utilizes this method to determine solubility parameters under controlled laboratory conditions.

Summary

The water-soluble film is held stationary in a prescribed plastic fixture and immersed in a beaker of water at a specified temperature. The time taken for a water-soluble film to disintegrate and dissolve is measured and recorded.

Significance

This is a method for determining the disintegration and relative dissolution time of a water-soluble film. Since this product is water soluble, the time and temperature at which the film disintegrates and dissolves is of practical significance.

Apparatus

1. Beaker, 600 ml
2. Magnetic Stirrer, Labline Model No. 1250 or equivalent
3. Magnetic stirring rod - 5 cm
4. Thermometer, 0 to 100°C, accurate to +/-1°C
5. Template, stainless steel 3.8 cm x 3.2 cm
6. Timer, accurate to the nearest second and measuring 0 to 300 seconds
7. Polaroid 35mm Slide Mounts or equivalent
8. Mono-Sol 35mm Slide Mount Holder or equivalent (see Figure 1)
9. Distilled water

Test Specimen

1. The test specimen shall consist of samples cut using the template.
2. For Quality Assurance purposes, three evenly spaced samples are to be taken in a straight line in the transverse direction (one from both sides and the other from the middle) of the film sample.
3. For Product Compatibility Testing (PCT), three specimens are initially tested, followed by individual samples obtained from all exposed film specimens.



Standard Test Method for Solubility of MonoSol® Water Soluble Film when contained within a Plastic Holder

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Conditioning

No conditioning is necessary. Testing by Quality Assurance (QA) may be performed immediately upon receipt of film samples from production. For Product Compatibility Testing, the test should be performed as soon as possible after removal of product and cleaning of the film specimen.

Procedure

1. For Quality Assurance purposes, use the template to cut three evenly spaced samples from the transverse direction of the web. For Product Compatibility Testing, three unexposed film specimens are initially tested, followed by individual samples obtained from all subsequent exposed film specimens.
2. Lock each of the samples in a separate 35mm slide mount.
3. Fill the beaker with 500ml of distilled water. Refer to the Process Specification Booklet or PCT protocol for specific water temperature to be used.
4. Mark the height of the column of water. Place the beaker on the magnetic stirrer, turn it on, and adjust until a vortex develops which is one-fifth the height of the column. Mark the depth of the vortex (Use this as a reference for all future testing).
5. Clamp the 35mm slide mount in the alligator jaws of the MonoSol 35mm slide mount holder such that the long end of the slide mount is parallel to the water surface (Figure 2). The depth adjustment of the clamping device should be set so that when dropped, the end of the clamp will be 0.6 cm below the surface of the water. One of the short sides of the slide mount should be next to the side of the beaker with the other positioned directly over the center of the stirring rod such that the film surface is perpendicular to the flow of the water (see attached).
6. In one motion, drop the secured slide and clamp into the water and start the timer. Disintegration occurs when the film breaks. When all visible film is released from the slide mount, raise the slide out of the water while continuing to monitor the solution for undissolved film fragments. Dissolution occurs when all film fragments are no longer visible and the solution becomes clear or the test is stopped at 300 seconds, whichever comes first.

Results

The results shall include the following:

1. Complete sample identification.
2. Individual and average disintegration and dissolution times.
3. Water temperature at which the samples were tested.
4. All data is recorded in the Production Database or PCT laboratory notebook.

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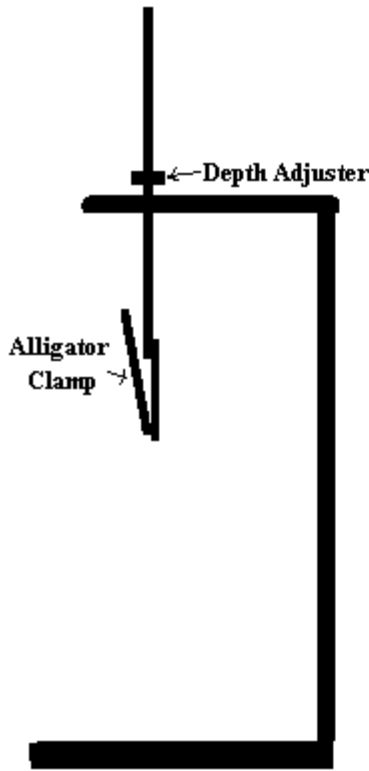


Figure 1

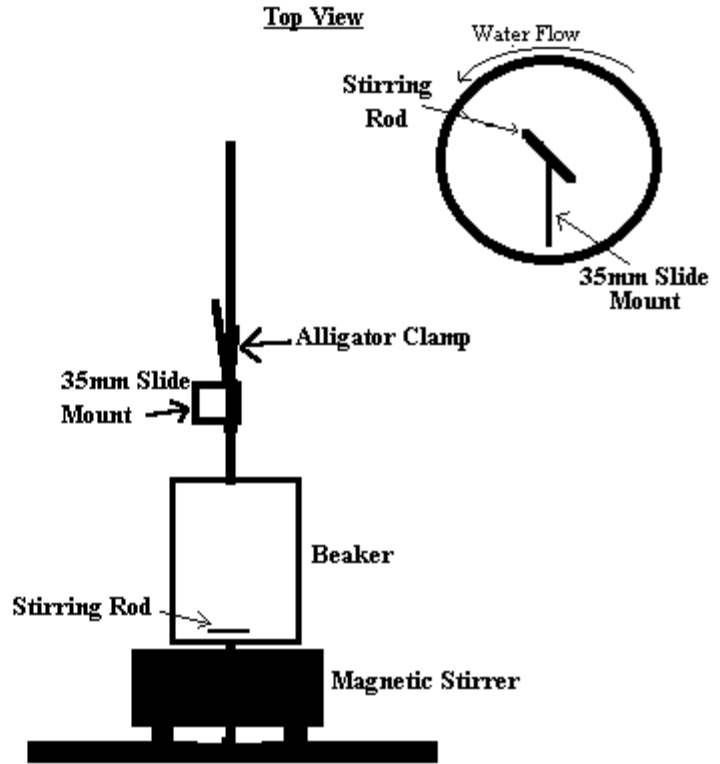


Figure 2