

Identification, Gel Formation Test

Applicable Products: Carbopol[®]* Polymers and Noveon[®]* AA-1 Polycarbophil

Scope:

This procedure describes a means of identification of Carbopol[®] polymers and Noveon[®] AA-1 polycarbophil. A dispersion of the powder forms a viscous gel when neutralized with sodium hydroxide.

Abstract:

A 1.0% dispersion of Carbopol[®] polymer or Noveon[®] AA-1 polycarbophil is prepared. The dispersion is neutralized with 1 N sodium hydroxide (see Special Instruction 1). A viscous gel is produced when the dispersion is neutralized to a pH of approximately 7.5.

Safety Precautions:

1. Wear safety goggles and gloves and follow good laboratory practices.
2. Polymer dust is irritating to the respiratory passages and inhalation should be avoided.
3. Sodium hydroxide solutions will cause burns to the skin and eyes. Flush any contact site with large quantities of water.
4. See all Material Safety Data Sheets (MSDS) for additional safety and handling information.

Interferences:

Inorganic salts can interfere with the formation of the gel.

Apparatus:

1. Laboratory balance capable of ± 0.01 gram accuracy.
2. Laboratory mixer with three-blade marine impeller (See Appendix I).
3. Mixer with 3.25-inch "S"-blade stirrer. (See Appendix II for diagram of "S"-blade).
4. Beaker, 800 ml.
5. Graduated cylinder, 500 ml.
6. Spatula or rubber policeman.
7. Weighing dish.
8. pH meter equipped with a calomel-glass electrode.

Reagents:

1. Deionized water.
2. Sodium hydroxide solution, 1 N. (See Special Instruction 1 for preparation of 1 N sodium hydroxide from pellets.)

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Procedure:

1. With the mixer in the off position, set the shaft angle at 60° and the mixer speed at 1000 rpm.
2. Measure 500 mL deionized water in a graduated cylinder and transfer to an 800 mL beaker.
3. Set the beaker under the mixer with the impeller to one side and as near the bottom of the beaker as possible. (See Note 1).
4. Weigh out 5 ± 0.01 grams of the polymer onto a weighing dish. This will yield a 1% dispersion in the 500 mL water.
5. Turn on the mixer and carefully begin to add the polymer. Tilt the weighing dish and tap the side, causing the polymer to slowly sift into the water. Total addition time should be 45-90 seconds. CAUTION: If addition is too rapid, the polymer will agglomerate on the surface of the water.
6. Continue mixing for 15 minutes at 1000 rpm. Scrape any polymer from the sides of the beaker and stirrer shaft with a spatula or rubber policeman.
7. When the mixing is complete, remove the stirrer from the dispersion.
8. Allow the dispersion to stand for 30 minutes to assure complete hydration.
9. With the "S" blade mixer off, set the paddle at a depth below the surface so that air will not be drawn into the mucilage. Adjust the speed of the mixer to approximately 300 rpm. Turn the mixer on and add the 1 N sodium hydroxide. Stir for 2 minutes, moving the beaker up and down. (If the "S" blade mixer is not available, see Special Instruction 2.)
10. Confirm the pH is approximately 7.5.
11. A viscous gel will result from the neutralization to a pH of approximately 7.5 if the material being tested is a Carbopol® polymer or Noveon® AA-1 polycarbophil.

Calculations:

The result of the test is recorded as pass or fail.

Special Instructions:

1. Preparation of 1 N Sodium Hydroxide:

The 1 N sodium hydroxide can be prepared from pellets. Slowly add 40 grams of sodium hydroxide pellets to 500 ml deionized water in a 1000 mL volumetric flask. Use caution as considerable heat will be generated as the sodium hydroxide dissolves. After cooling, dilute to the mark with water. (The 1 N sodium hydroxide may be purchased.)

2. If the "S"-blade mixer is not available, a laboratory spatula is effective for accomplishing the mixing.

Notes:

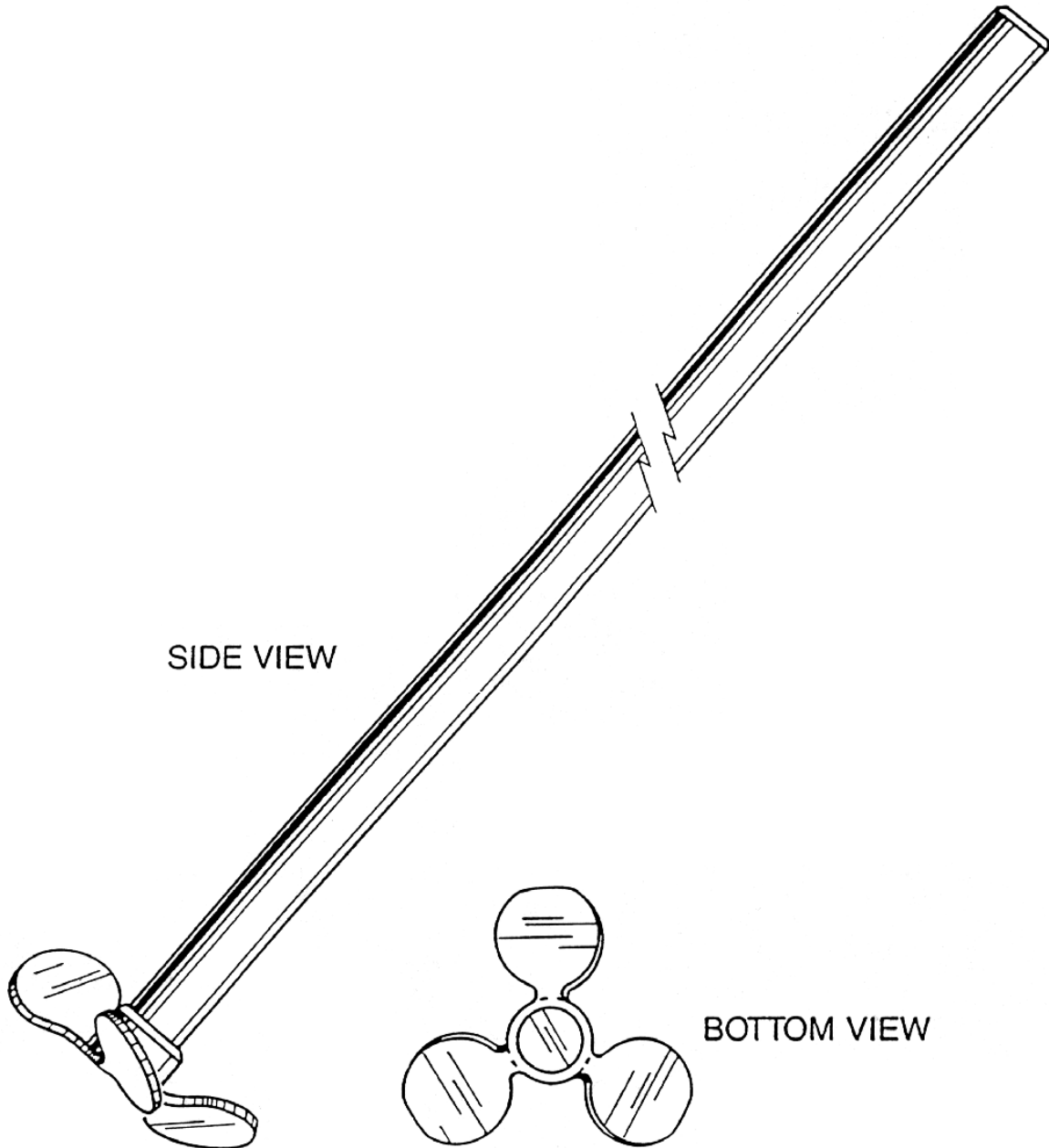
1. The angle of 60° and placement of the stirring shaft to one side of the beaker creates vigorous agitation with a minimum of vortexing.

References:

- *Current edition of the US Pharmacopoeia/ National Formulary (USP/NF)*
- *Current edition of the European Pharmacopoeia*

Appendix I
(Actual Size)

Three-Blade Marine Impeller



Appendix II
(Actual Size)

“S”-Blade Impeller

