

Test Procedure SA-026 Edition: August, 2010

# Identification, Colorimetric Test Applicable Products: Carbopol<sup>®</sup>\* Polymers and Noveon<sup>®</sup>\* AA-1 Polycarbophil

### Scope:

This procedure describes a colorimetric means of identification of Carbopol<sup>®</sup> polymers and Noveon<sup>®</sup> AA-1 polycarbophil. A 1% dispersion will give an orange color with thymol blue solution and a yellow color with a cresol red solution.

### Abstract:

Five hundred milliliters of a 1% dispersion of Carbopol<sup>®</sup> polymer or Noveon<sup>®</sup> AA-1 polycarbophil is prepared. Thymol blue is added to an aliquot of the dispersion producing an orange color. To a second aliquot, the addition of cresol red produces a yellow color.

### **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. See all Material Safety Data Sheets (MSDS) for additional safety and handling information.

### Interferences:

Any acidic and basic systems inadvertently introduced into the test would influence the results, as the indicators measure pH.

### **Apparatus:**

- 1. Laboratory balance capable of  $\pm\,0.01$  gram accuracy.
- Laboratory mixer with three-blade marine impeller. (See Appendix I for diagram of threeblade marine impeller.)
- 3. Beakers, 800 mL.
- 4. Graduated cylinder, 500 mL.
- 5. Spatula or rubber policeman.
- 6. Weighing dish.
- 7. Graduated cylinder, 10 mL.
- 8. Beaker, 50 mL.
- 9. Pipette, 1 mL.
- 10. Pipette bulb.

### **Reagents:**

- 1. Deionized water.
- Thymol blue TS (USP), 0.1% alcoholic solution. (See Special Instruction 1.)
- Cresol red TS (USP). (See Special Instruction 2.)

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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.
- Measure 500 mL deionized water in a graduated cylinder and transfer to an 800 mL beaker.
- 3. Place the beaker under the mixer with the impeller to one side of the beaker. The impeller should be as near the bottom of the beaker as possible. (See Note 1)
- 4. Weigh 5  $\pm$  0.01 grams of the product onto a weighing dish. This will yield a 1% dispersion in 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. Incomplete hydration could influence the results of the test.
- 6. Continue vigorous mixing for 15 minutes. During mixing, scrape any polymer from the sides of the beaker and stirrer shaft with a spatula or rubber policeman.
- 7. Remove the dispersion from the stirrer and allow to stand for 30 minutes to assure complete polymer hydration.
- 8. Transfer 10 mL of the dispersion to a 50 ml beaker.
- Add 0.5 mL thymol blue TS to the dispersion using a 1 mL pipette and mix. An orange color is produced.
- 10. To a second beaker, transfer a 10 mL aliquot of the dispersion.
- 11. Add 0.5 mL cresol red TS and mix. A yellow color is produced.
- 12. The combination of positive results from the indicator tests is a confirmation of identity for a Carbopol<sup>®</sup> polymer or Noveon<sup>®</sup> AA-1 polycarbophil.

# Calculations:

The results of the test are recorded as pass or fail.

# **Special Instructions:**

- 1. Thymol blue TS (0.1% alcoholic solution) can be purchased. To prepare, dissolve 100 mg of thymol blue in 100 ml alcohol and filter if necessary.
- Cresol red TS (0.04% aqueous solution) can be purchased. To prepare, triturate100 mg of cresol red in a mortar with 26.2 ml 0.01 N sodium hydroxide until solution is complete. Dilute the solution with water to 250 ml.

# 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 United States Pharmacopoeia/ National Formulary (USP/NF)
- Current edition of the European Pharmacopoeia

