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# Polycarbophil

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CAS RN®: 9003-97-8; UNII: 8F049NKY49.

» Polycarbophil is polyacrylic acid cross-linked with divinyl glycol.

**Packaging and storage**—Preserve in tight containers.

**Identification**—

**A:** A dispersion (1 in 100) is orange with thymol blue TS and yellow with cresol red TS.

**B:** Adjust a dispersion (1 in 100) with 1 M sodium hydroxide to a pH of about 7.5. A very viscous gel is produced.

**pH** ⟨791⟩—To 1.0 g add 100 mL of water, and shake by mechanical means for 1 hour: the pH of the mixture is not more than 4.0.

**Loss on drying** ⟨731⟩—Dry it in vacuum at 45° for 4 hours: it loses not more than 1.5% of its weight.

**Residue on ignition** ⟨281⟩: not more than 4.0%.

**Absorbing power**—Transfer about 50 mg, accurately weighed, to an accurately tared 50-mL centrifuge tube fitted with a tight closure. Add 35 mL of sodium bicarbonate solution (1.5 in 100), and shake manually, venting as necessary to release liberated carbon dioxide. Shake and vent at least 3 times. Close the tube tightly, and shake vigorously by mechanical means for 60 minutes. Centrifuge at 2000 rpm for 1 hour. By means of a 50-mL syringe fitted with a 13-gauge needle, draw off the supernatant taking care that the solid material is not disturbed. Repeat the process of the addition of 35 mL of sodium bicarbonate solution, of the shaking, and of the withdrawing of supernatant. Accurately weigh the tube with its contents, and calculate the weight of the absorbed solution by subtracting the weight of Polycarbophil taken and the tare weight of the tube. The absorbed weight is not less than 62 g per g of Polycarbophil on the dried basis.

**Limit of acrylic acid**—

*pH 3.0 phosphate buffer*—Prepare 0.01 M monobasic potassium phosphate, and adjust with phosphoric acid to a pH of 3.0 ± 0.5.

*Mobile phase*—Prepare a degassed solution consisting of *pH 3.0 phosphate buffer* and methanol (8:2).

*Standard solution*—Dissolve an accurately weighed quantity of acrylic acid in water to obtain a solution containing 1.0 mg per mL. Dilute quantitatively, and stepwise if necessary, with a 2.5% alum solution to obtain a solution having a known concentration of about 30 µg per mL.

*Test solution*—Transfer about 0.1 g of Polycarbophil into a vial. Add 20 mL of a 2.5% alum solution and mix. Heat at 50° for 20 minutes, then shake for 1 hour, centrifuge, and filter.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 210-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 2.0 mL per minute. Chromatograph the *Standard solution*, and record peak responses as directed for *Procedure:* the relative standard deviation for replicate injections of the *Standard solution* is not more than 5.0%, and the tailing factor is not more than 2.5.

*Procedure*—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the response for the acrylic acid peak. Calculate the percentage of acrylic acid in the portion of Polycarbophil taken by the formula:

$$(0.002C/W)(r_U/r_S)$$

in which $C$ is the concentration, in µg per mL, of acrylic acid, $W$ is the weight, in g, of Polycarbophil taken, and $r_U$ and $r_S$ are the acrylic acid peak responses obtained from the *Test solution* and the *Standard solution*, respectively: not more than 0.3% acrylic acid is found.

**Limit of ethyl acetate**—

*Internal standard solution*—Dissolve an accurately weighed quantity of methyl ethyl ketone in methanol, and dilute quantitatively, and stepwise if necessary, to obtain a solution having a known concentration of about 0.075 mg per mL.

*Standard solution*—Dissolve 0.225 mg, accurately weighed, of ethyl acetate into a 10-mL volumetric flask. Add 2.0 mL of the *Internal standard solution*, dilute with methanol to volume, and mix.

*Test solution*—Transfer about 50 mg of Polycarbophil into a 10-mL volumetric flask. Add 2.0 mL of the *Internal standard solution*, dilute with methanol to volume, and mix.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The gas chromatograph is equipped with a flame-ionization detector and a 10-ft. × 2-mm column that contains 1% liquid phase G25 on support S12. The column is maintained at about 160°, and the injection port and detector block are maintained at about 250°. The carrier gas is dry helium flowing at a rate of about 30 mL per minute. Chromatograph the *Standard solution*, and record the chromatogram as directed for *Procedure:* the relative retention times are about 1.3 for ethyl acetate, and 1.0 for methyl ethyl ketone, and the relative standard deviation for replicate injections of the ethyl acetate peak is not more than 2%. *Procedure*—Separately inject equal volumes (about 2 µL) of the *Test solution* and the *Standard solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of ethyl acetate in the portion of Polycarbophil taken by the formula:

$$(0.001C/W)(R_U/R_S)$$

in which $C$ is the concentration of ethyl acetate, in µg per mL, $W$ is the weight of Polycarbophil, in g, and $R_U$ and $R_S$ are the ratios of the responses of the ethyl acetate peak to the methyl ethyl ketone peak obtained from the *Test solution* and the *Standard solution*, respectively: not more than 0.45% is found.

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
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**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
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