

U.S. PHARMACOPEIA

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Methacrylic Acid Copolymer

» Methacrylic Acid Copolymer is a fully polymerized copolymer of methacrylic acid and an acrylic or methacrylic ester. Type C may contain suitable surface-active agents. The assay and viscosity requirements differ for the several types, as set forth in the accompanying table.

Type	Methacrylic acid units, dried basis (%)		Viscosity (cps)	
	Min.	Max.	Min.	Max.
A	46.0	50.6	50	200
B	27.6	30.7	50	200
C	46.0	50.6	100	200

Packaging and storage— Preserve in tight containers.

Labeling— Label it to state whether it is Type A, B, or C.

USP Reference standards [〈 11 〉](#) — [USP Methacrylic Acid Copolymer, Type A RS.](#) [USP Methacrylic Acid Copolymer, Type B RS.](#) [USP Methacrylic Acid Copolymer, Type C RS.](#)

Identification—

A: [Infrared Absorption](#) [〈 197K 〉](#).

B: Pour a few mL of the solution prepared for the *Viscosity* test onto a glass plate, and allow the solvent to evaporate: a clear, brittle film results.

Viscosity [〈 911 〉](#) — Place 254.6 g of isopropyl alcohol and 7.9 g of water in a conical flask having a ground-glass joint. Add a quantity of Methacrylic Acid Copolymer, accurately weighed and equivalent to 37.5 g of solids on the dried basis, while stirring by means of a magnetic stirrer. Close the flask, and continue stirring until the polymer has dissolved completely. Adjust the temperature to $20 \pm 0.1^\circ$. Equip a suitable rotational viscosimeter with a spindle having a cylinder 1.88 cm in diameter and 6.25 cm high attached to a shaft 0.32 cm in diameter, the distance from the top of the cylinder to the lower tip of the shaft being 0.75 cm, and the immersion depth being 8.15 cm (No. 1 spindle). With the spindle rotating at 30 rpm, immediately observe and record the scale reading. Convert the scale reading to centipoises by multiplying the reading by the constant for the viscosimeter spindle and speed employed.

Loss on drying [〈 731 〉](#) — Dry it at 110° for 6 hours: it loses not more than 5.0% of its weight.

Residue on ignition [〈 281 〉](#): not more than 0.1% for Types A and B; not more than 0.4% for Type C.

[Heavy metals, Method II](#) [〈 231 〉](#): 0.002%.

Change to read:

Limit of monomers—

pH 2.0 Phosphate buffer, 0.025 M [NF24](#)—Prepare an aqueous solution containing 3.550 g of **anhydrous** [NF24](#) dibasic sodium phosphate (Na_2HPO_4) and 3.400 g of monobasic potassium phosphate (KH_2PO_4) per L. Adjust with phosphoric acid to a pH of 2.0.

Mobile phase— Prepare a solution in methanol to contain 700 mL of **pH 2.0 Phosphate buffer, 0.025 M** [NF24](#) per L.

Standard solution— Prepare a solution in methanol to contain an accurately known concentration of about 2.4 μg per mL each of methacrylic acid and either methyl methacrylate (for Type A and Type B) or ethyl acrylate (for Type C). To 50.0 mL of this solution, add 25.0 mL of water, and mix.

Test solution— Dissolve about 40 mg of Methacrylic Acid Copolymer, accurately weighed, in 50.0 mL of methanol, add 25.0 mL of water, and mix.

Chromatographic system (see [Chromatography](#) [〈 621 〉](#))— The liquid chromatograph is equipped with a 202-nm detector and a 4-mm \times 12.5-cm column that contains 5- μm packing L1. The flow rate is about 2.5 mL per minute. Chromatograph the **Standard solution**, and record the peak responses as directed for **Procedure**: the resolution, R , of each pair of analytes is not less than 2.0; the capacity factors, k' , for methacrylic acid, ethyl acrylate, and methyl methacrylate are 1.7, 4.3, and 4.8, respectively; and the relative standard deviation for replicate injections determined from each analyte is not more than 2%.

Procedure— Separately inject equal volumes (about 50 μL) of the **Standard solution** and the **Test solution** into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in μg , of each monomer in the portion of Methacrylic Acid Copolymer taken by the formula:

$$75C(r_U / r_S)$$

in which C is the concentration, in μg per mL, of the monomer in the **Standard solution**; and r_U and r_S are the peak responses for the monomer obtained from the **Test solution** and the **Standard solution**, respectively.

Not more than 0.05% of total monomers is found.

[Organic volatile impurities, Method V](#) [〈 467 〉](#): meets the requirements.

Solvent— Use dimethyl sulfoxide.

[Residual solvents](#) [〈 467 〉](#): meets the requirements.

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Assay— Dissolve about 1 g of Methacrylic Acid Copolymer, previously dried and accurately weighed, in 100 mL of neutralized acetone, add 1 drop of phenolphthalein TS, and titrate with 0.1 N sodium hydroxide VS until a pink color persists for 15 seconds. Each mL of 0.1 N sodium hydroxide is equivalent to 8.609 mg of methacrylic acid ($\text{C}_4\text{H}_6\text{O}_2$) units.

Auxiliary Information— *Staff Liaison* : [Hong Wang, Ph.D. , Senior Scientific Associate](#)

Expert Committee : (EM205) Excipient Monographs 2

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