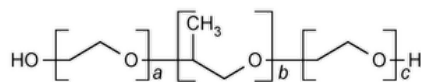


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## Poloxalene



Oxirane, methyl-, polymer with oxirane.

Polyethylene-polypropylene glycol

CAS RN<sup>®</sup>: 9003-11-6.

» Poloxalene is a synthetic block copolymer of ethylene oxide and propylene oxide. It contains not less than 98.0 percent and not more than 103.0 percent of poloxalene.

**Packaging and storage**—Preserve in tight containers, protected from light. Store in a cool place.

**USP REFERENCE STANDARDS (11)**—

[USP Poloxalene RS](#)

**Labeling**—Label it to indicate that it is for veterinary use only.

**Identification**—

*Color reagent*—Dissolve 12.7 g of ammonium thiocyanate and 2.0 g of cobalt nitrate in 100 mL of water.

*Procedure*—Add 10 mL of ethylene chloride to 0.5 g of Poloxalene, and shake for 1 minute. Add 1 mL of *Color reagent*, and shake for 1 minute: a blue color is produced in the lower layer.

**Average molecular weight**—

*Phthalic anhydride-pyridine solution*—Prepare as directed in the test for *Average molecular weight* under [Poloxamer](#).

*Procedure*—Using about 12 g of Poloxalene, accurately weighed, proceed as directed for *Procedure* in the test for *Average molecular weight* under [Poloxamer](#): the average molecular weight is between 2850 and 3150.

**pH (791)**: between 5.0 and 7.5, in a solution (1 in 40).

**WATER DETERMINATION, Method Ia (921)**: not more than 0.4%.

**HYDROXYL VALUE (401)**—

*Esterification reagent*—Dissolve 166 g of phthalic anhydride and 28 g of imidazole in 1000 mL of pyridine, and allow to stand for 2 hours before using. Store in a light-resistant bottle.

*Procedure*—Transfer a quantity of Poloxalene, determined by dividing 420 by the expected hydroxyl value and accurately weighed, to a glass-stoppered, 250-mL conical flask, and add 25.0 mL of *Esterification reagent*. Transfer 25.0 mL of *Esterification reagent* to a second glass-stoppered, 250-mL conical flask to provide the reagent blank. Add glass beads to the flasks, swirl to dissolve the Poloxalene, and fit both flasks with glass-jointed reflux condensers previously rinsed with 10 mL of pyridine, and heat on a steam bath for 15 minutes. Add 10 mL of pyridine through each condenser, insert the stoppers, and cool under running water for 1 minute. After removing the condensers, add 10 mL of water and 1 mL of phenolphthalein TS, and titrate with 0.5 N sodium hydroxide VS to a light pink endpoint that persists for at least 15 seconds. Calculate the hydroxyl value by the formula:

$$(56.11N/W)(B - U)$$

in which *N* is the normality of the 0.5 N sodium hydroxide titrant; *W* is the weight, in g, of the Poloxalene taken; *B* and *U* are the volumes, in mL, of 0.5 N sodium hydroxide consumed by the reagent blank and the solution of Poloxalene, respectively. [NOTE—If *B* minus *U* is greater than 10 mL, repeat the test using a smaller sample.] The hydroxyl value is between 36.0 and 40.0.

**Cloud point**—Add 10 g of Poloxalene to 190.0 mL of water in a 250-mL beaker. Add a magnetic stirring bar, place on a stirrer and hot plate, and stir until dissolution is complete. Place a probe from an electronic thermometer with an accuracy of 0.2° in the solution within 3 mm of the stirring bar. Continue stirring at a rate that minimizes the formation of bubbles. Adjust the hot plate so that the temperature of the solution increases at a rate of about 1° per minute. Continue to view the solution, and record the temperature when the probe can no longer be seen. This occurs between 42.5° and 46.5°.

**Assay**—

*Standard preparation*—Dissolve an accurately weighed quantity of [USP Poloxalene RS](#) in ethylene dichloride to obtain a solution having a known concentration of about 0.1575 mg per mL.

*Assay preparation*—Transfer about 105 mg of Poloxalene, accurately weighed, to a 100-mL volumetric flask, add about 85 mL of ethylene dichloride, and swirl to dissolve. Dilute with ethylene dichloride to volume, and mix. Transfer 15.0 mL of this solution to a second 100-mL volumetric flask, dilute with ethylene dichloride to volume, and mix.

*Procedure*—Transfer 10.0 mL of the *Standard preparation*, the *Assay preparation*, and ethylene dichloride (to serve as a blank) to glass-stoppered tubes, add 4.0 mL of the *Color reagent* specified in the *Identification* test, shake vigorously for 3 minutes, and then centrifuge for 5 minutes. Carefully remove the lower ethylene dichloride layers from the three tubes, and using the ethylene dichloride layer from the tube containing the blank to zero the spectrophotometer, determine the UV absorbance at 630 nm of the solutions from the *Standard preparation* and the *Assay preparation*. Calculate the percentage of poloxalene in the portion of Poloxalene taken by the formula:

$$100(A_u/A_s)(C_s/C_u)$$

in which  $A_u$  and  $A_s$  are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively; and  $C_s$  and  $C_u$  are the concentrations, in mg per mL, of the *Standard preparation* and the *Assay preparation*, respectively.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
POLOXALENE	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM32020 Small Molecules 3

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