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Resorcinol and Sulfur Topical Suspension

» Resorcinol and Sulfur Topical Suspension is Resorcinol and Sulfur in a suitable hydroalcoholic vehicle. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of resorcinol ($C_6H_6O_2$) and not less than 95.0 percent and not more than 110.0 percent of the labeled amount of sulfur (S).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Resorcinol RS

Identification—

A: Transfer a quantity of Topical Suspension, equivalent to about 20 mg of resorcinol, to a 15-mL centrifuge tube, add 5 mL of 5 N sodium hydroxide, mix, and centrifuge the mixture for 5 minutes. Decant the supernatant into a test tube, and retain the residue for *Identification* test *B*. Add 0.5 mL of chloroform, mix, and heat on a steam bath: an intense crimson color is produced. Add a slight excess of hydrochloric acid: the color changes to pale yellow *(presence of resorcinol)*.

B: Place a small portion of the residue from the centrifuge tube in *Identification* test *A* on the tip of a spatula, and burn it: sulfur dioxide, which turns moistened starch-iodate paper blue, is formed *(presence of sulfur)*.

Alcohol Determination ⟨611⟩ —Determine by the gas-liquid chromatographic method, acetone being used as the internal standard: it contains between 90.0% and 110.0% of the labeled amount of C_2H_5OH.

Assay for resorcinol—

Mobile phase—Prepare a suitable degassed solution of water, acetonitrile, and methanol (about 55:7:6) such that the retention times of resorcinol and caffeine are about 3 minutes and 4 minutes, respectively.

Internal standard solution—Dissolve about 140 mg of caffeine in 2 mL of chloroform, add methanol to make 100 mL, and mix.

Standard preparation—Transfer 50 mg of USP Resorcinol RS, accurately weighed, to a 25-mL volumetric flask, dilute with methanol to volume, and mix. Transfer 10.0 mL of this solution and 5.0 mL of *Internal standard solution* to a 100-mL volumetric flask, dilute with methanol to volume, and mix.

Assay preparation—Transfer an accurately weighed portion of Topical Suspension, equivalent to about 20 mg of resorcinol, to a 150-mL beaker. Add 40 mL of methanol and 5.0 mL of *Internal standard solution,* and heat on a steam bath for 5 minutes. Cool the mixture to room temperature, and decant the liquid into a 100-mL volumetric flask. Wash the residue in the beaker by adding 20 mL of methanol to the beaker. Heat on a steam bath for 5 minutes, cool the mixture to room temperature, and decant the liquid into the volumetric flask. Repeat the washing, heating, cooling, and decanting. Dilute the contents of the volumetric flask with methanol to volume, and mix.

Procedure—Introduce equal volumes (about 10 µL) of the *Assay preparation* and the *Standard preparation* into a high-pressure liquid chromatograph (see *Chromatography ⟨621⟩*), operated at room temperature, by means of a suitable microsyringe or sampling valve, adjusting the specimen size and other operating parameters such that the peak obtained from the *Standard preparation* is about 0.6 full scale. Typically, the apparatus is fitted with a 4-mm × 30-cm column containing packing L1 and is equipped with an UV detector capable of monitoring absorption at 280 nm, and a suitable recorder. In a suitable chromatogram the coefficient of variation for five replicate injections of the *Standard preparation* is not more than 3.0%. Measure the peak responses at equivalent retention times, obtained from the *Assay preparation* and the *Standard preparation,* and calculate the quantity, in mg, of resorcinol ($C_6H_6O_2$) in the portion of Topical Suspension taken by the formula:

$$(100C)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Resorcinol RS in the *Standard preparation;* and R_U and R_S are the ratios of the responses of the resorcinol and caffeine peaks obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Assay for sulfur—Transfer an accurately weighed portion of Topical Suspension, equivalent to about 85 mg of sulfur, to a suitable flask, add 40 mL of sodium sulfite solution (1 in 20), a few drops of antifoam, and a few boiling chips, and boil under a reflux condenser for 1 hour. Cool to room temperature, add 10 mL of formaldehyde solution and 6 mL of 6 N acetic acid, and dilute with water to 150 mL. Add 3 mL of starch TS, and titrate with 0.1 N iodine VS until a permanent blue color is produced. Each mL of 0.1 N iodine is equivalent to 3.206 mg of sulfur (S).

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

Topic/Question	Contact	Expert Committee
RESORCINOL AND SULFUR TOPICAL SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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