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Hydroquinone Topical Solution

» Hydroquinone Topical Solution contains not less than 95.0 percent and not more than 110.0 percent of the labeled amount of hydroquinone ($C_6H_6O_2$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Hydroquinone RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

pH ⟨791⟩: between 3.0 and 4.2.

Assay—

Mobile phase—Mix 55 volumes of methanol and 45 volumes of water.

Standard preparation—Transfer about 250 mg of USP Hydroquinone RS, accurately weighed, to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Transfer 3.0 mL of this solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Topical Solution, equivalent to about 30 mg of hydroquinone, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 0.8 mL per minute. Chromatograph three replicate injections of the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative standard deviation is not more than 3.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph by means of a suitable microsyringe or sampling valve, record the chromatograms, and measure the responses for the major peaks. The retention time is about 4 minutes for hydroquinone. Calculate the quantity, in mg, of hydroquinone ($C_6H_6O_2$) in each mL of the Topical Solution taken by the formula:

$$100(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Hydroquinone RS in the *Standard preparation*; V is the volume, in mL, of Topical Solution taken; and r_U and r_S are the peak responses of hydroquinone obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
HYDROQUINONE TOPICAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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