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# Cholestyramine for Oral Suspension

» Cholestyramine for Oral Suspension is a mixture of Cholestyramine Resin with suitable excipients and coloring and flavoring agents. It contains not less than 85.0 percent and not more than 115.0 percent of the labeled amount of dried cholestyramine resin.

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

**USP Reference standards ⟨11⟩**—
USP Cholestyramine Resin RS

**Identification**—Transfer a quantity of Cholestyramine for Oral Suspension, equivalent to about 500 mg of dried cholestyramine resin, to a suitable flask, add 100 mL of 0.1 N hydrochloric acid, stir to suspend the solid, and heat on a steam bath for 10 minutes. Filter, wash the residue with three 50-mL portions of water, and dry at 70° and at a pressure not exceeding 50 mm of mercury for 16 hours: the IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Cholestyramine Resin RS.

**Uniformity of dosage units ⟨905⟩**: meets the requirements for *Weight Variation*.

**Assay**—

*Mobile phase*, *Potassium phosphate buffer*, *Sodium glycocholate solution*, *Reference solution*, *Standard solution*, *System suitability solution*, and *Chromatographic system*—Proceed as directed in the test for *Exchange capacity* under *Cholestyramine Resin*.

*Test solution*—Transfer an accurately weighed portion of Cholestyramine for Oral Suspension, equivalent to about 100 mg of cholestyramine resin, to a 25-mL conical flask. Pipet 15.0 mL of *Sodium glycocholate solution* into the flask, and stir by mechanical means for 2 hours. Transfer the contents to a centrifuge tube, and centrifuge for 15 minutes. Transfer 5.0 mL of the supernatant to a 50-mL volumetric flask, and dilute with water to volume.

*Procedure*—Separately inject equal volumes (about 50 µL) of the *Reference solution*, 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 mg, of cholestyramine resin per mg of Cholestyramine for Oral Suspension taken by the formula:

$$[M(2.5r_R - r_U)W_S] / [(2.5r_R - r_S)W_UQ]$$

in which $M$ is the stated value, in mg, of sodium glycocholate absorbed per g of USP Cholestyramine Resin RS; $r_R$, $r_U$, and $r_S$ are the peak responses obtained from the *Reference solution*, the *Test solution*, and the *Standard solution*, respectively; $W_S$ is the weight, in mg, of USP Cholestyramine Resin RS taken to prepare the *Standard solution*; $W_U$ is the weight, in mg, of Cholestyramine for Oral Suspension taken to prepare the *Test solution*; and $Q$ is the quantity of sodium glycocholate absorbed per g of dried cholestyramine resin, as obtained in the test for *Exchange capacity* under *Cholestyramine Resin*.



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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| CHOLESTYRAMINE FOR ORAL SUSPENSION | Documentary Standards Support | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

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