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Ursodiol Capsules

» Ursodiol Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ursodiol ($C_{24}H_{40}O_4$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Ursodiol 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,* both relative to the internal standard, as obtained in the *Assay.*

Dissolution ⟨711⟩—

Medium: 0.05 M pH 8.4 phosphate buffer, prepared by mixing 250 mL of 0.2 M monobasic potassium phosphate, 280 mL of 0.2 M potassium hydroxide, and 5 mL of 2% sodium lauryl sulfate solution. Adjust with 0.2 M potassium hydroxide to a pH of 8.4, and dilute with water to 1000 mL; 1000 mL.

Apparatus 2: 75 rpm.

Time: 30 minutes.

Determine the amount of ursodiol ($C_{24}H_{40}O_4$) dissolved by employing the following method.

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile and 0.075 M monobasic potassium phosphate (50:50). Adjust with 85% phosphoric acid to a pH of 3.0. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard solution—Dissolve an accurately weighed quantity of USP Ursodiol RS, and dilute quantitatively, and stepwise if necessary, with *Medium* to obtain a solution having a known concentration equivalent to that expected in the solution under test.

Test solution—Use a filtered portion of the solution under test.

Chromatographic system—The liquid chromatograph is equipped with a refractive index detector, a guard column that contains packing L1, and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1 mL per minute, and the column and detector temperatures are maintained at 40°. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the tailing factor of the ursodiol peak is not more than 1.7; and the relative standard deviation for replicate injections 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 percentage of $C_{24}H_{40}O_4$ dissolved by the formula:

$$100{,}000(r_U/r_S)(C/W)$$

in which r_U and r_S are the peak responses obtained from the *Test solution* and the *Standard solution,* respectively; C is the concentration, in mg per mL, of USP Ursodiol RS in the *Standard solution;* and W is the labeled amount, in mg, of ursodiol in each Capsule.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{24}H_{40}O_4$ is dissolved in 30 minutes.

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

Assay—

Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Ursodiol.*

Assay preparation—Accurately weigh the contents of not fewer than 20 Capsules, and mix. Transfer an accurately weighed portion of the powder, equivalent to about 200 mg of ursodiol, to a 50-mL volumetric flask. Add about 40 mL of methanol, and sonicate for about 15 minutes. Cool the mixture to room temperature, dilute with methanol to volume, and centrifuge a portion of this mixture. Transfer 5.0 mL of the clear supernatant to a 25-mL volumetric flask, and dilute with *Mobile phase* to volume. Transfer equal amounts of this solution and the *Internal standard solution* to a suitable container, mix, and filter.

Procedure—Separately inject equal volumes (about 50 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of ursodiol ($C_{24}H_{40}O_4$) in the portion of Capsules taken by the formula:

$$200(C_S/C_U)(R_U/R_S)$$

in which C_S and C_U are the concentrations, in mg per mL, of ursodiol in the *Standard preparation* and the *Assay preparation*, respectively; and R_U and R_S are the ratios of the ursodiol peak to the internal standard peak 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
URSODIOL CAPSULES	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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