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Hydrocortisone Rectal Suspension

» Hydrocortisone Rectal Suspension contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Hydrocortisone RS

Identification, *Thin-Layer Chromatographic Identification Test* ⟨201⟩—

Test solution—Use the *Assay preparation*, except to omit addition of the *Internal standard solution*.

pH ⟨791⟩**:** between 5.5 and 7.0.

Assay—

Mobile phase—Mix 55 mL of a solution of water in methanol (5 in 100) with 1.0 mL of glacial acetic acid, dilute with water-washed 1,2-dichloroethane to 1000 mL, and mix. Degas before using. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Dissolve 200 mg of acetaminophen in 4 mL of methanol, dilute with water-washed 1,2-dichloroethane to 200 mL, and mix. Keep the solution tightly stoppered and protected from light.

Standard preparation—Accurately weigh about 8 mg of USP Hydrocortisone RS, add 4 mL of methanol and 4.0 mL of *Internal standard solution*, dilute with chloroform to 100.0 mL, and mix to obtain a solution having a known concentration of about 0.08 mg of USP Hydrocortisone RS per mL.

Assay preparation—Transfer an accurately weighed quantity of Rectal Suspension, equivalent to about 8 mg of hydrocortisone, to a separator. Extract with four 20-mL portions of chloroform, filtering each portion through chloroform-washed cotton into a 100-mL volumetric flask. Add 4 mL of methanol and 4.0 mL of *Internal standard solution*, dilute with chloroform to volume, and mix. Pass the extract through a 0.5-µm porosity polytef membrane filter, discarding the first 20 mL of the filtrate.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L3. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 1.3 for acetaminophen and 1.0 for hydrocortisone; the resolution, *R,* between the analyte and internal standard is not less than 2.5; the column efficiency determined from the analyte peak is not less than 5000 theoretical plates; and the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 10 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 hydrocortisone ($C_{21}H_{30}O_5$) in the portion of Rectal Suspension taken by the formula:

$$100C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Hydrocortisone RS in the *Standard preparation;* and R_U and R_S are the peak response ratios 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
HYDROCORTISONE RECTAL SUSPENSION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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