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Hydrocortisone Acetate Lotion

» Hydrocortisone Acetate Lotion is Hydrocortisone Acetate in a suitable aqueous vehicle. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of hydrocortisone acetate ($C_{23}H_{32}O_6$).

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)—
[USP Hydrocortisone Acetate RS](#)

Identification—It responds to the [Identification](#) test under [Hydrocortisone Acetate Ointment](#).

MINIMUM FILL (755): meets the requirements.

Assay—

Mobile phase—Prepare a filtered and degassed solution containing butyl chloride, water-saturated butyl chloride, tetrahydrofuran, methanol, and glacial acetic acid (475:475:70:35:30). Make adjustments if necessary (see [System Suitability](#) under [Chromatography \(621\)](#)).

Standard preparation—Dissolve an accurately weighed quantity of [USP Hydrocortisone Acetate RS](#) in water-saturated chloroform to obtain a solution having a known concentration of about 0.10 mg per mL.

Assay preparation—Transfer an accurately weighed quantity of Lotion, equivalent to about 2.5 mg of hydrocortisone acetate, to a closable container. Add 25.0 mL of water-saturated chloroform and about 10 glass beads. Securely close the container, and shake vigorously for approximately 15 minutes. Centrifuge, and use the clear, lower chloroform layer.

Procedure—Introduce equal volumes of the *Assay preparation* and the *Standard preparation* into a high-pressure liquid chromatograph fitted with a 254-nm detector. Typically the apparatus is fitted with a 4-mm × 30-cm column containing packing L3 and operated at room temperature. Six replicate injections of the *Standard preparation* show a relative standard deviation of not more than 2.0%. Calculate the quantity, in mg, of hydrocortisone acetate ($C_{23}H_{32}O_6$) in the portion of Lotion taken by the formula:

$$25C(r_u/r_s)$$

in which C is the concentration, in mg per mL, of [USP Hydrocortisone Acetate RS](#) in the *Standard preparation*; and r_u and r_s are the hydrocortisone acetate peak responses 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 ACETATE LOTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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