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# Crotamiton Cream

» Crotamiton Cream contains not less than 93.0 percent and not more than 107.0 percent of the labeled amount of $C_{13}H_{17}NO$.

**Packaging and storage**—Preserve in collapsible tubes or tight, light-resistant containers.

**USP Reference standards ⟨11⟩**—

USP Crotamiton RS

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

**Minimum fill ⟨755⟩**: meets the requirements.

**Assay**—

*Internal standard solution*—Dissolve butyl benzoate in methanol to obtain a solution containing about 17.5 mg per mL.

*Mobile phase*—Prepare a suitable degassed and filtered mixture of acetonitrile and water (3:2).

*Standard solution*—Dissolve a suitable quantity of USP Crotamiton RS, accurately weighed, in methanol to obtain a solution having a known concentration of about 1 mg per mL.

*Standard preparation*—Pipet 10 mL of *Standard solution* and 5 mL of *Internal standard solution* into a 50-mL volumetric flask, dilute with methanol to volume, and mix.

*Assay preparation*—Transfer an accurately weighed portion of Crotamiton Cream, equivalent to about 50 mg of crotamiton, to a tared 50-mL volumetric flask. Add about 25 mL of methanol, and shake and sonicate to disperse the cream. Dilute with methanol to volume, and mix. Filter about 20 mL through moderately retentive filter paper. Pipet 10 mL of the clear filtrate and 5 mL of *Internal standard solution* into a 50-mL volumetric flask, dilute with methanol to volume, and mix.

*Procedure*—Inject equal volumes of the *Standard preparation* and the *Assay preparation* into a liquid chromatograph (see *Chromatography ⟨621⟩*) equipped with a 254-nm detector and a 4.6-mm × 25-cm stainless steel column that contains packing L1. In a suitable chromatogram, the resolution, *R*, between peaks for crotamiton and butyl benzoate is not less than 3.0; and the lowest and highest peak response ratios ($R_S$) of three replicate injections of the *Standard preparation* agree within 2.0%. Calculate the quantity, in mg, of $C_{13}H_{17}NO$ in the portion of Cream taken by the formula:

$$250C(R_U/R_S)$$

in which *C* is the concentration, in mg per mL, of USP Crotamiton RS in the *Standard preparation;* and $R_U$ and $R_S$ are the peak response ratios of the crotamiton peak and the butyl benzoate 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 |
|---|---|---|
| CROTAMITON CREAM | Documentary Standards Support | SM12020 Small Molecules 1 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
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