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## Anthralin Cream

### DEFINITION

Anthralin Cream is Anthralin in an aqueous (oil-in-water) or oily (water-in-oil) cream vehicle. Cream labeled to contain more than 0.1% of anthralin contains NLT 90.0% and NMT 115.0% of the labeled amount of anthralin ( $C_{14}H_{10}O_3$ ), and Cream labeled to contain 0.1% or less of anthralin contains NLT 90.0% and NMT 130.0% of the labeled amount of anthralin ( $C_{14}H_{10}O_3$ ).

### ASSAY

#### • PROCEDURE

[NOTE—Use low-actinic glassware.]

**Mobile phase:** *n*-Hexane, dichloromethane, and glacial acetic acid (82:12:6)

**Internal standard solution:** 0.5 mg/mL of *o*-nitroaniline in *n*-hexane prepared as follows. First dissolve *o*-nitroaniline in a small quantity of dichloromethane, and then dilute with *n*-hexane.

**System suitability stock solution:** 0.1 mg/mL of [USP Anthralin RS](#) and 0.2 mg/mL of danthron in dichloromethane

**System suitability solution:** Transfer 5 mL of the *System suitability stock solution* into a 25-mL volumetric flask, add 5 mL of *n*-hexane, and dilute with *Mobile phase* to volume.

**Solvent blank solution:** *Mobile phase*, *n*-hexane, and dichloromethane (3:1:1)

**Standard stock solution:** 0.25 mg/mL of [USP Anthralin RS](#) in dichloromethane

**Standard solution:** Transfer 2 mL each of *Standard stock solution* and *Internal standard solution* into a 25-mL volumetric flask, and dilute with *Mobile phase* to volume.

**Sample stock solution:** Weigh 5 g of Cream into a 100-mL beaker. Add 20 mL of dichloromethane and 10 mL of glacial acetic acid, and stir to disperse the Cream. Transfer the contents of the beaker to a filter paper (Whatman No. 4, or equivalent) with the aid of dichloromethane, and filter into a 100-mL volumetric flask. Thoroughly wash the precipitate with dichloromethane, and allow the washings to drain into the flask. Dilute with dichloromethane to volume.

**Sample solution:** Transfer a volume of *Sample stock solution* equivalent to 0.5 mg of anthralin and 2 mL of *Internal standard solution* into a 25-mL volumetric flask, and dilute with *Mobile phase* to volume.

#### Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** UV 354 nm

**Column:** 4.6-mm × 25-cm; packing L3

**Flow rate:** 2 mL/min

**Injection volume:** 10 µL

#### System suitability

**Samples:** *System suitability solution*, *Solvent blank solution*, and *Standard solution*

[NOTE—The relative retention times for anthralin, danthron, dianthrone, and *o*-nitroaniline are 1.0, 1.2, 1.7, and 2.3, respectively.]

#### Suitability requirements

**Resolution:** NLT 1.3 between anthralin and danthron, *System suitability solution*

**Tailing factor:** NMT 1.5, *System suitability solution*

**Relative standard deviation:** NMT 2.0% of the ratio of the peak responses, *Standard solution*

**Interference:** No discernible signal is observed at the retention time of anthralin, *Solvent blank solution*

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of anthralin ( $C_{14}H_{10}O_3$ ) in the portion of Cream taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

$R_U$  = peak response ratio of anthralin to *o*-nitroaniline from the *Sample solution*

$R_S$  = peak response ratio of anthralin to *o*-nitroaniline peak from the *Standard solution*

$C_S$  = concentration of [USP Anthralin RS](#) in the *Standard solution* (µg/mL)

$C_U$  = nominal concentration of anthralin in the *Sample solution* (µg/mL)

**Acceptance criteria:** 90.0%–115.0% for Cream labeled to contain more than 0.1% of anthralin; 90.0%–130.0% for Cream labeled to contain 0.1% or less of anthralin

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, in a cool place. Protect from light.
- **LABELING:** Label it to indicate whether the cream vehicle is aqueous or oily.
- **USP REFERENCE STANDARDS** (11).  
[USP Anthralin RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ANTHRALIN CREAM	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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