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Anthralin Ointment

DEFINITION

Anthralin Ointment is Anthralin in a petrolatum or other oleaginous vehicle. Ointment 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 Ointment 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 Ointment into a 100-mL beaker. Add 20 mL of dichloromethane and 10 mL of glacial acetic acid, and stir to disperse the Ointment. 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 Ointment 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 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 Ointment labeled to contain more than 0.1% of anthralin; 90.0%–130.0% for Ointment 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.
- **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 OINTMENT	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](#)

Most Recently Appeared In:

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