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Decoquinat Type A Medicated Article

(Title for this monograph not to change until December 1, 2017)

(Prior to December 1, 2017, the current practice of labeling the article of commerce with the name Decoquinat Premix may be continued. Use of the name Decoquinat Type A Medicated Article will be permitted as of June 1, 2017; however, the use of this name will not be mandatory until December 1, 2017.)

DEFINITION

Decoquinat Type A Medicated Article contains NLT 90.0% and NMT 110.0% of the labeled amount of decoquinat ($C_{24}H_{35}NO_5$), the labeled amount being between 1 g/100 g and 10 g/100 g of Decoquinat Type A Medicated Article.

IDENTIFICATION

• A.

Standard solution: 2.5 mg/mL of [USP Decoquinat RS](#) in [chloroform](#)

Sample solution: To a weighed quantity of sample, equivalent to 100 mg of decoquinat, add 40 mL of [chloroform](#), and heat under a reflux condenser on a water bath for 20 min, cool, and filter. Use the filtrate as the *Sample solution*.

Chromatographic system

(See [Chromatography \(621\), General Procedures, Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: [Chloroform](#) and [alcohol](#) (70:30)

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Standard solution* and *Sample solution* to the starting line of the chromatographic plate. Allow the spots to dry, and develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate.

Remove the plate from the developing chamber, and allow to dry in a current of air. Locate the spots under short-wavelength UV light.

Acceptance criteria: The R_f value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• PROCEDURE

Standard solution: 0.005 mg/mL of [USP Decoquinat RS](#) prepared as follows. Transfer 50 mg of [USP Decoquinat RS](#) to a 100-mL volumetric flask, add 10 mL of hot [chloroform](#), swirl to dissolve, and while still warm, slowly add 70 mL of [dehydrated alcohol](#). Allow to cool, and dilute with [dehydrated alcohol](#) to volume. Immediately transfer 10.0 mL of this solution to a second 100-mL volumetric flask, and dilute with [dehydrated alcohol](#) to volume. Transfer 10.0 mL of this solution to a third 100-mL volumetric flask, add 10 mL of 0.1 N [hydrochloric acid](#), and dilute with [dehydrated alcohol](#) to volume.

Sample solution: Extract an accurately weighed quantity of Decoquinat Type A Medicated Article, equivalent to 200 mg of decoquinat, with 50 mL of [chloroform](#) in a small continuous extraction apparatus for eight reflux cycles. Transfer the extract to a 100-mL volumetric flask with the aid of [chloroform](#), cool, and dilute with [chloroform](#) to volume. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, and dilute with [dehydrated alcohol](#) to volume. Transfer 5.0 mL of this solution to a third 100-mL volumetric flask, add 10 mL of 0.1 N [hydrochloric acid](#), and dilute with [dehydrated alcohol](#) to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 265 nm

Blank: [Chloroform](#), [dehydrated alcohol](#), and 0.1 N [hydrochloric acid](#) (0.25:90:10)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the label amount of decoquinat ($C_{24}H_{35}NO_5$) in the portion of Decoquinat Type A Medicat Article taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Decoquinat RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of decoquinat in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Label it to indicate that it is for veterinary use only.
- **USP REFERENCE STANDARDS (11).**
[USP Decoquinat RS](#)

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

Topic/Question	Contact	Expert Committee
DECOQUINAT TYPE A MEDICATED ARTICLE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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