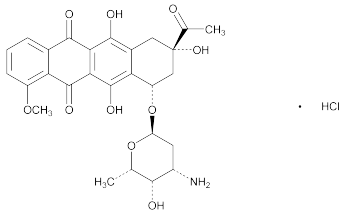
Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of dapsone, to a 200-mL volumetric flask. Add 150 mL of methanol, and place the flask in an ultrasonic bath at a temperature of 35 ° for 15 minutes, with occasional shaking. Allow to cool to room temperature, add methanol to volume, and mix. Centrifuge a portion of the mixture until clear. Transfer 5.0 mL of the clear supernatant to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Dapsone*. Calculate the quantity, in mg, of $C_{12}H_{12}N_2O_2S$ in the portion of Tablets taken by the formula:

$$2C(P_U / P_S).$$

Daunorubicin Hydrochloride



$C_{27}H_{29}NO_{10} \cdot HCl$ 563.98

5,12-Naphthacenedione, 8-acetyl-10-[(3-amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-, (8*S*-*cis*)-, hydrochloride.

(1*S*,3*S*)-3-Acetyl-1,2,3,4,6,11-hexahydro-3,5,12-trihydroxy-10-methoxy-6,11-dioxo-1-naphthacenyl 3-amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranoside hydrochloride [23541-50-6].

» Daunorubicin Hydrochloride has a potency equivalent to not less than 842 µg and not more than 1030 µg of $C_{27}H_{29}NO_{10}$ per mg.

Caution—Great care should be taken to prevent inhaling particles of Daunorubicin Hydrochloride and exposing the skin to it.

Packaging and storage—Preserve in tight containers, protected from light and excessive heat.

USP Reference standards ⟨11⟩**—**
USP Daunorubicin Hydrochloride RS

Identification—

A: The IR absorption spectrum of a potassium bromide dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of USP Daunorubicin Hydrochloride RS.

B: The retention time of the main peak obtained with the *Assay preparation* corresponds to that obtained with the *Standard preparation* as directed in the *Assay*.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 4.5 and 6.5, in a solution containing 5 mg per mL.

Water, *Method I* ⟨921⟩: not more than 3.0%.

Assay—

Mobile phase—Mix 62 volumes of water and 38 volumes of acetonitrile, and adjust with phosphoric acid to a pH of 2.2 ± 0.2. The acetonitrile concentration may be varied to meet system suitability requirements and to provide a suitable elution time for daunorubicin. Filter the solution through a membrane filter (1 µm or finer porosity), and degas.

Standard preparation—Dissolve an accurately weighed quantity of USP Daunorubicin Hydrochloride RS in *Mobile phase* to obtain a solution having a known concentration of about 250 µg of daunorubicin per mL.

Resolution solution—Prepare a solution of doxorubicin hydrochloride in the *Standard preparation* containing about 250 µg per mL.

Assay preparation—Transfer about 25 mg of Daunorubicin Hydrochloride, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The chromatograph is equipped with a 254-nm detector and a 4.6-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.7 for doxorubicin and 1.0 for daunorubicin; and the resolution, *R,* between the doxorubicin peak and the daunorubicin peak is not less than 3. Chromatograph replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 5 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the potency, in µg of $C_{27}H_{29}NO_{10}$ per mg, taken by the formula:

$$100(C / W)(r_U / r_S)$$

in which C is the concentration, in µg per mL, of daunorubicin in the *Standard preparation; W* is the weight, in mg, of Daunorubicin Hydrochloride taken; and r_U and r_S are the daunorubicin peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Daunorubicin Hydrochloride for Injection

» Daunorubicin Hydrochloride for Injection is a sterile mixture of Daunorubicin Hydrochloride and Mannitol. It contains the equivalent of not less than 90.0 per cent and not more than 115.0 percent of the labeled amount of $C_{27}H_{29}NO_{10}$.

Packaging and storage—Preserve in light-resistant *Containers for Sterile Solids* as described under *Injections* ⟨1⟩.

USP Reference standards ⟨11⟩**—**
USP Daunorubicin Hydrochloride RS
USP Endotoxin RS

Constituted solution—At the time of use, it meets the requirements for *Constituted Solutions* under *Injections* ⟨1⟩.

Identification—The retention time of the main peak obtained with the *Assay preparation* corresponds to that obtained with the *Standard preparation* as directed in the *Assay*.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 4.3 USP Endotoxin Units per mg of daunorubicin.

pH ⟨791⟩: between 4.5 and 6.5, in the solution constituted as directed in the labeling.

Water, *Method I* ⟨921⟩: not more than 3.0%, the *Test Preparation* being prepared as directed for a hygroscopic specimen.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—

Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Prepare as directed in the *Assay* under *Daunorubicin Hydrochloride*.

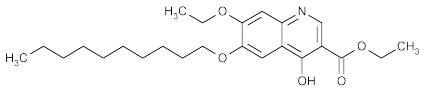
Assay preparation—Transfer the contents of 1 vial of Daunorubicin Hydrochloride for Injection with the aid of *Mobile phase* to an appropriate volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution containing about 0.25 mg of daunorubicin per mL.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Daunorubicin Hydrochloride*. Calculate the quantity, in mg, of $C_{27}H_{29}NO_{10}$ in the vial of Daunorubicin Hydrochloride for Injection taken by the formula:

$$(CV / 1000)(r_U / r_S)$$

in which V is the volume, in mL, of the *Assay preparation*, and the other terms are as defined therein.

Decoquinate



$C_{24}H_{35}NO_5$ 417.54

3-Quinolinecarboxylic acid, 6-(decyloxy)-7-ethoxy-4-hydroxy-, ethyl ester.

Ethyl 6-(decyloxy)-7-ethoxy-4-hydroxy-3-quinolinecarboxylate [18507-89-6].

» Decoquinate contains not less than 99.0 percent and not more than 101.0 per cent of $C_{24}H_{35}NO_5$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—
USP Decoquinate RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: Transfer about 40 mg of it, accurately weighed, to a 100-mL volumetric flask, add 10 mL of hot chloroform, swirl to dissolve, and while still warm add about 60 mL of dehydrated alcohol. Allow to cool, dilute with dehydrated alcohol to volume, and mix. Promptly transfer 10.0 mL of this solution to a second 100-mL volumetric flask, dilute with dehydrated alcohol to volume, and mix. Transfer 10.0 mL of this solution to a third 100-mL volumetric flask, add 10 mL of 0.1 N hydrochloric acid, dilute with dehydrated alcohol to volume, and mix: the UV absorption spectrum of this solution exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Decoquinate RS, concurrently measured, and the respective absorptivities, calculated on the dried basis, at the wavelength of maximum absorption at about 265 nm do not differ by more than 2.5%.

Loss on drying ⟨731⟩—Dry it at 105 ° to constant weight: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Ordinary impurities ⟨466⟩—

Test solution: chloroform, prepared with the aid of heat.

Standard solution: chloroform, using dilutions of the *Test solution*.

Eluant: a mixture of chloroform, dehydrated alcohol, and anhydrous formic acid (85:10:5).

Visualization: 1.

Tolerances: no impurity exceeds 1%, and the total does not exceed 2%.

Assay—Dissolve about 1000 mg of Decoquinate, accurately weighed, in 100 mL of glacial acetic acid, with the aid of gentle heat. Allow to cool, add 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid VS to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 41.76 mg of $C_{24}H_{35}NO_5$.

Decoquinate Premix

» Decoquinate Premix contains not less than 90.0 percent and not more than 110.0 per cent of the labeled amount of $C_{24}H_{35}NO_5$, the labeled amount being between 1 g and 10 g per 100 g of Premix.

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 Decoquinate RS

Identification—To an accurately weighed quantity of it, equivalent to about 100 mg of decoquinate, add 40 mL of chloroform, and heat under a reflux condenser on a water bath for 20 minutes, cool, and filter. Use the filtrate as the test solution. Apply 10-µL portions of the test solution and of a Standard solution in chloroform containing 2.5 mg of USP Decoquinate RS per mL to the starting line of a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of chloroform and alcohol (70:30) 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: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

Assay—Extract an accurately weighed quantity of Premix, equivalent to about 200 mg of decoquinate, with 50 mL of chloroform in a small continuous extraction apparatus for 8 reflux cycles. Transfer the extract to a 100-mL volumetric flask with the aid of chloroform, cool, dilute with chloroform to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, dilute with dehydrated alcohol to volume, and mix. Transfer 5.0 mL of this solution to a third 100-mL volumetric flask, add 10 mL of 0.1 N hydrochloric acid, dilute with dehydrated alcohol to volume, and mix (*Assay preparation*). Transfer 50 mg of USP Decoquinate RS, accurately weighed, 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, dilute with dehydrated alcohol to volume, and mix. Immediately transfer 10.0 mL of this solution to a second 100-mL volumetric flask, dilute with dehydrated alcohol to volume, and mix. Transfer 10.0 mL of this solution to a third 100-mL volumetric flask, add 10 mL of 0.1 N hydrochloric acid, dilute with dehydrated alcohol to volume, and mix. This *Standard preparation* contains about 0.005 mg of USP Decoquinate RS per mL. Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* at the wavelength of maximum absorbance at about 265 nm, with a spectrophotometer, using a mixture of dehydrated alcohol, 0.1 N hydrochloric acid, and chloroform (90:10:0.25) as the blank. Calculate the percentage of $C_{24}H_{35}NO_5$ in the portion of Premix taken by the formula:

$$4000(C / W)(A_U / A_S)$$

in which C is the concentration, in mg per mL, of USP Decoquinate RS in the *Standard preparation; W* is the quantity, in g, of Premix taken to prepare the *Assay preparation;* and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation,* respectively.