Chloramphenicol Palmitate Oral Suspension

» Chloramphenicol Palmitate Oral Suspension contains the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$). It contains one or more suitable buffers, colors, flavors, preservatives, and suspending agents.

Packaging and storage— Preserve in tight, light-resistant containers.

USP Reference standards ⟨ 11 ⟩ — *USP Chloramphenicol Palmitate RS* . *USP Chloramphenicol Palmitate Polymorph A RS*. *USP Chloramphenicol Palmitate Nonpolymorph A RS*.

Identification— The retention time of the chloramphenicol palmitate peak in the chromatogram of the *Assay preparation* corresponds to that of the chloramphenicol palmitate peak in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

Uniformity of dosage units ⟨ 905 ⟩ —

F OR SUSPENSION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨ 698 ⟩ : meets the requirements.

pH ⟨ 791 ⟩ : between 4.5 and 7.0.

Limit of polymorph A—

Standard preparation— Prepare a dry mixture of 1 part by weight of *USP Chloramphenicol Palmitate Polymorph A RS* and 9 parts by weight of *USP Chloramphenicol Palmitate Nonpolymorph A RS*. Prepare a 1 in 3 mineral oil dispersion of this mixture, and place a portion of it between two sodium chloride plates, taking care not to allow air bubbles to form.

Test preparation— Place 20 mL of previously mixed Oral Suspension in a 50-mL centrifuge tube, add 20 mL of water, and mix. Centrifuge, and discard the supernatant solution. Add 20 mL of water to the residue in the centrifuge tube, mix, centrifuge, and discard the supernatant solution. Repeat this washing two times. Dry the residue in vacuum over silica gel for not less than 14 hours. Prepare a 1 in 3 mineral oil dispersion of the dried residue, and place a portion of it between two sodium chloride plates, taking care not to allow air bubbles to form.

Procedure— Concomitantly record the absorption spectra of the *Standard preparation* and the *Test preparation* from about 11 µm to about 13 µm, with a suitable infrared absorption spectrophotometer, using an empty cell to set the instrument to 100 percent transmittance. Adjust the cell thickness of the *Standard preparation* and of the *Test preparation* so that transmittances of 20% to 30% are obtained at 12.3 µm. On each spectrum, draw a straight baseline between the absorption minima at wavelengths of about 11.3 µm and 12.65 µm. Draw straight lines, perpendicular to the wavelength scale, at the wavelengths of maximum absorption at about 11.65 µm and 11.86 µm, intersecting both the baseline and the spectrum. Determine the absorbance ratio:

$$(A_{11.65a} - A_{11.65b}) / (A_{11.86a} - A_{11.86b}),$$

in which the parenthetic expressions are the differences in absorbance values obtained at the wavelengths indicated by the subscripts for the spectrum (*a*) and at the point of intersection of the

perpendicular line with the baseline (*b*). The absorbance ratio of the *Test preparation* is greater than that of the *Standard preparation*, corresponding to not more than 10% of polymorph A.

Assay—

Mobile phase , *Standard preparation*, and *Chromatographic system* —Proceed as directed in the *Assay* under *Chloramphenicol Palmitate*.

Assay preparation— Transfer an accurately measured volume of Oral Suspension, well-shaken and free from air bubbles, equivalent to about 160 mg of chloramphenicol, to a 200-mL volumetric flask containing about 20 mL of methanol, add 4 mL of glacial acetic acid, dilute with methanol to volume, and mix. Filter about 20 mL of this solution through glass-fiber filter paper. Transfer 10.0 mL of the filtrate to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

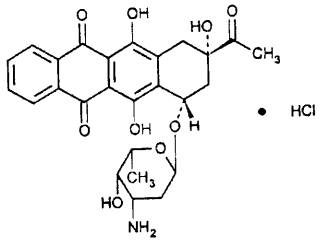
Procedure— Proceed as directed for *Procedure* in the *Assay* under *Chloramphenicol Palmitate*. Calculate the quantity, in mg, of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) equivalent in each mL of Oral Suspension taken by the formula:

$$0.004(W_S / V)(P_S)(r_U / r_S),$$

in which V is the volume, in mL, of Oral Suspension taken, and the other terms are as defined therein.

Auxiliary Information—
Staff Liaison : William W. Wright, Ph.D., Senior Scientist
Expert Committee : (PA7) Pharmaceutical Analysis 7 — Antibiotics
USP–NF : Page No. 383
Pharmacopeial Forum : Volume No. 22 Page No. 3128
Phone Number : 1-301-816-8335

Idarubicin Hydrochloride



$C_{26}H_{27}NO_9$ HCl 533.95

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

(1*S*,3 *S*)-3-Acetyl-1,2,3,4,6,11-hexahydro-3,5,12-trihydroxy-6,11-dioxo-1-naphthacenyl 3-amino-2,3,6-trideoxy-α- L- *lyxo*-hexopyranoside, hydrochloride [*57852-57-0*].

» Idarubicin Hydrochloride contains not less than 960 µg and not more than 1030 µg of $C_{26}H_{27}NO_9$ HCl per mg, calculated on the anhydrous basis. ***Caution—*** *Great care should be taken to prevent inhaling particles of Idarubicin Hydrochloride and exposing the skin to it.*

Packaging and storage— Preserve in tight containers.

USP Reference standards <11> — *USP Idarubicin Hydrochloride RS* .

Identification—

A: *Infrared Absorption* ⟨ 197K ⟩ .

B: The chromatogram of the *Assay preparation* obtained in the *Assay* exhibits a major peak for idarubicin, the retention time of which corresponds to that in the chromatogram of the *Standard preparation* obtained in the *Assay*.

Crystallinity ⟨ 695 ⟩ : meets the requirements.

pH ⟨ 791 ⟩ : between 5.0 and 6.5, in a solution containing 5 mg per mL.

Water, *Method I* ⟨ 921 ⟩ : not more than 5.0%.

Chromatographic purity— Using the chromatogram of the *Assay preparation* obtained in the *Assay*, and disregarding the solvent peak, calculate the percentage of each impurity taken by the formula:

$$100r_i / r_S,$$

in which r_i is the response of each impurity peak, and r_S is the sum of the responses of all the peaks: not more than 1.0% of any individual impurity is found, and the sum of all impurities is not more than 3.0%.

Assay—

Mobile phase— Prepare a mixture of water, acetonitrile, methanol, and phosphoric acid (540:290:170:2). Dissolve 1 g of sodium lauryl sulfate in 1000 mL of this solution, adjust with 2 N sodium hydroxide to a pH