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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)—

FOR 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. Add 20 mL of water to the residue in the centrifuge tube, mix, centrifuge, and discard the supernatant. 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 μ m to about 13 μ m, with a suitable IR 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 μ m. On each spectrum, draw a straight baseline between the absorption minima at wavelengths of about 11.3 μ m and 12.65 μ m. Draw straight lines, perpendicular to the wavelength scale, at the wavelengths of maximum absorption at about 11.65 μ m and 11.86 μ m, 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 parenthetical 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.

Topic/Question	Contact	Expert Committee
CHLORAMPHENICOL PALMITATE ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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