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Chloramphenicol Palmitate

$C_{27}H_{42}Cl_2N_2O_6$ 561.54

Hexadecanoic acid, 2-[(2,2-dichloroacetyl)amino]-3-hydroxy-3-(4-nitrophenyl)propyl ester, [*R*-(*R**,*R**)]-.

D-*threo*-(−)-2,2-Dichloro-*N*-[β-hydroxy-α-(hydroxymethyl)-*p*-nitrophenethyl]acetamide α-palmitate CAS RN®: 530-43-8; UNII: 43VU4207NW.

» Chloramphenicol Palmitate has a potency equivalent to not less than 555 µg and not more than 595 µg of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) per mg.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Chloramphenicol Palmitate 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*.

Melting range ⟨741⟩: between 87° and 95°.

Specific rotation ⟨781S⟩: between +21° and +25°.

Test solution: 50 mg, undried, per mL, in dehydrated alcohol.

Crystallinity ⟨695⟩: meets the requirements.

Loss on drying ⟨731⟩—Dry it to constant weight over phosphorus pentoxide in vacuum at a pressure not exceeding 5 mm of mercury: it loses not more than 0.5% of its weight.

Acidity—Dissolve 1.0 g by heating at 35° with 5 mL of a 1:1 mixture of 80 percent alcohol and ether, previously neutralized using phenolphthalein TS. Titrate with 0.1 N sodium hydroxide VS, using phenolphthalein TS, until on gentle shaking a pink color persists for not less than 30 seconds: not more than 0.4 mL is consumed.

Free chloramphenicol—Dissolve 1.0 g in 80 mL of xylene with the aid of gentle warming. Cool, and extract with three 15-mL portions of water, combining the aqueous extracts and discarding the xylene. Dilute the combined aqueous extracts with water to 50 mL, extract with 10 mL of toluene, allow to separate, and discard the toluene. Centrifuge a portion of the aqueous solution, and determine the absorbance of the clear solution at the wavelength of maximum absorbance at about 278 nm, using a suitable spectrophotometer, and using as a reagent blank to set the instrument to zero the solution obtained by the same procedure without the specimen: the absorbance is not more than 0.268 (0.045%).

Assay—

Mobile phase—Prepare a suitable degassed mixture of methanol, water, and glacial acetic acid (172:27:1).

Standard preparation—Transfer about 65 mg of USP Chloramphenicol Palmitate RS to a 50-mL volumetric flask, add about 40 mL of methanol and 1 mL of glacial acetic acid, and sonicate for a few minutes. Dilute with methanol to volume, and mix. Transfer 10.0 mL of this solution to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Assay preparation—Using about 65 mg of Chloramphenicol Palmitate, accurately weighed, prepare as directed under *Standard preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 3.9-mm × 30-cm column that contains 10-µm packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the column efficiency determined from the analyte peak is not less than 2400 theoretical plates, and the relative standard deviation for replicate injections is not more than 0.5%.

Procedure—Separately inject equal volumes (about 10 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 quantity, in µg, of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) equivalent in each mg of specimen taken by the formula:

$$(W_S/W_U)(P_S)(r_U/r_S)$$

in which W_S and W_U are the quantities, in mg, of USP Chloramphenicol Palmitate RS and Chloramphenicol Palmitate taken, respectively; P_S is the designated chloramphenicol equivalent, in µg per mg, of USP Chloramphenicol Palmitate RS; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Chromatographic Database Information: Chromatographic Database

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