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Chloramphenicol Sodium Succinate

$C_{15}H_{15}Cl_2N_2NaO_8$ 445.18

Butanedioic acid, mono[2-[(2,2-dichloroacetyl)amino]-3-hydroxy-3-(4-nitrophenyl)propyl] ester, monosodium salt, [*R*-(*R**,*R**)]-.

D-*threo*-(−)-2,2-Dichloro-*N*-[β-hydroxy-α-(hydroxymethyl)-*p*-nitrophenethyl]acetamide α-(sodium succinate) CAS RN®: 982-57-0; UNII: 872109HX6B.

» Chloramphenicol Sodium Succinate has a potency equivalent to not less than 650 µg and not more than 765 µg of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) per mg.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is intended for use in preparing sterile dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of sterile dosage forms.

USP Reference standards ⟨11⟩—
USP Chloramphenicol RS

Identification—The *Assay preparation* exhibits an absorption maximum at a wavelength of about 276 nm, as obtained in the *Assay*.

Specific rotation ⟨781S⟩: between +5.0° and +8.0°.
Test solution: 50 mg per mL.

pH ⟨791⟩: between 6.4 and 7.0, in a solution containing the equivalent of 250 mg of chloramphenicol per mL.

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

Limit of free chloramphenicol—

Mobile phase—Prepare a filtered and degassed mixture of 0.05 M monobasic ammonium phosphate, previously adjusted with 10% (v/v) phosphoric acid to a pH of 2.5 ± 0.1, and methanol (60:40). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard solution—Dissolve an accurately weighed quantity of USP Chloramphenicol RS in *Mobile phase* to obtain a solution having a known concentration of about 6 µg per mL. Pass this solution through a filter having a 0.5-µm or finer porosity, and use the filtrate.

Test solution—Transfer about 33 mg of Chloramphenicol Sodium Succinate, accurately weighed, to a 50-mL volumetric flask. Dilute with *Mobile phase* to volume, and mix. Pass a portion of this solution through a filter having a 0.5-µm or finer porosity.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 275-nm detector and a 4.6-mm × 10-cm column that contains 5-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Test solution*, and record the peak responses as directed for *Procedure:* the column efficiency determined from the two major peaks, chloramphenicol-1-succinate and chloramphenicol-3-succinate, is not less than 1750 theoretical plates; the resolution, *R,* between the two peaks is not less than 2.0; and the tailing factor is not more than 1.2. Chromatograph the *Standard solution*, and record the peak areas as directed for *Procedure*: the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the areas for the free chloramphenicol peaks. Calculate the percentage of free chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) in the portion of Chloramphenicol Sodium Succinate taken by the formula:

$$5000(C/WQ)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Chloramphenicol RS in the *Standard solution; W* is the quantity, in mg, of Chloramphenicol Sodium Succinate taken to prepare the *Test solution; Q* is the quantity, in µg, of chloramphenicol in each mg of Chloramphenicol Sodium Succinate taken, as obtained in the *Assay;* and r_U and r_S are the peak areas obtained from the *Test solution* and the *Standard solution*, respectively. Not more than 2.0% is found.

Other requirements—Where the label states that Chloramphenicol Sodium Succinate is sterile, it meets the requirements for *Sterility* and *Bacterial endotoxins* under *Chloramphenicol Sodium Succinate for Injection*. Where the label states that Chloramphenicol Sodium Succinate must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Chloramphenicol Sodium Succinate for Injection*.

Assay—

Standard preparation—Dissolve an accurately weighed quantity of USP Chloramphenicol RS in water, and dilute quantitatively with water to obtain a solution having a known concentration of about 20 µg per mL.

Assay preparation—Dissolve an accurately weighed quantity of Chloramphenicol Sodium Succinate in water, and dilute quantitatively with water to obtain a solution having a concentration equivalent to about 20 µg of chloramphenicol per mL.

Procedure—Concomitantly determine the absorbance of the *Standard preparation*, at the wavelength of maximum absorbance at about 278 nm, and the absorbance of the *Assay preparation*, at the wavelength of maximum absorbance at about 276 nm, in 1-cm cells, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in µg, of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) in each mg of Chloramphenicol Sodium Succinate taken by the formula:

$$(CP/W)(A_U/A_S)$$

in which *C* is the concentration, in µg per mL, of USP Chloramphenicol RS in the *Standard preparation; P* is the potency, in µg per mg, of USP Chloramphenicol RS; *W* is the weight, in µg, of Chloramphenicol Sodium Succinate taken in each mL of the *Assay preparation;* and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

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