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Chloramphenicol Sodium Succinate for Injection

» Chloramphenicol Sodium Succinate for Injection contains an amount of Chloramphenicol Sodium Succinate equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$).

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

USP Reference standards ⟨11⟩—
USP Chloramphenicol RS

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.2 USP Endotoxin Unit per mg of chloramphenicol.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Limit of free chloramphenicol—

Mobile phase, Standard solution, and *Chromatographic system*—Proceed as directed in the test for *Limit of free chloramphenicol* under *Chloramphenicol Sodium Succinate*.

Test solution—Dissolve the contents of 1 container in a volume of *Mobile phase* to obtain a solution containing the equivalent of about 100 mg of chloramphenicol per mL. Dilute this solution quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution containing the equivalent of about 0.5 mg of chloramphenicol per mL. Pass a portion of this solution through a filter having a 0.5-µm or finer porosity, and use the filtrate.

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 specimen taken by the formula:

$$0.1(C/D)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Chloramphenicol RS in the *Standard solution; D* is the concentration, in mg per mL, of chloramphenicol equivalent in the *Test solution*, based on the labeled quantity in the container and the extent of dilution; and r_U and r_S are the chloramphenicol peak areas obtained from the *Test solution* and the *Standard solution*, respectively. Not more than 2.0% is found.

Other requirements—It meets the requirements of the tests for *Identification*, *Specific rotation*, *pH*, and *Water* under *Chloramphenicol Sodium Succinate*.

Assay—

Standard preparation—Proceed as directed in the *Assay* under *Chloramphenicol Sodium Succinate*.

Assay preparation—Constitute 1 container of Chloramphenicol Sodium Succinate for Injection as directed in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with water to obtain a solution having a concentration of about 20 µg of chloramphenicol per mL.

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

$$(L/D)(CP/1000)(A_U/A_S)$$

in which L is the labeled quantity, in mg, of chloramphenicol in each mL of constituted solution; D is the concentration, in µg per mL, of chloramphenicol in the *Assay preparation*, on the basis of the labeled quantity of chloramphenicol in each mL of constituted solution and the extent of dilution; 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; 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 FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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