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Chloramphenicol Injection

» Chloramphenicol Injection is a sterile solution of Chloramphenicol in one or more suitable solvents. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_{11}H_{12}Cl_2N_2O_5$. It may contain suitable buffers.

Packaging and storage—Preserve in single-dose or in multiple-dose containers.

Labeling—Label it to indicate that it is for veterinary use only.

USP REFERENCE STANDARDS (11)—
[USP Chloramphenicol RS](#)

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

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*, 1 mL from each container being transferred directly to the membrane filter.

pH (791): between 5.0 and 8.0, in a solution diluted with water (1:1).

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—

Mobile phase, Standard preparation, and Chromatographic system—Prepare as directed in the [Assay](#) under [Chloramphenicol](#).

Assay preparation—Transfer an accurately measured volume of Chloramphenicol Injection, equivalent to about 200 mg of chloramphenicol, to a 100-mL volumetric flask, add *Mobile phase* to volume, and mix. Transfer 4.0 mL of the resulting solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Filter this solution through a 0.5-µm or finer porosity filter.

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

$$2.5(C/V)(r_U/r_S)$$

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

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CHLORAMPHENICOL INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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