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Chloramphenicol Tablets

» Chloramphenicol Tablets contain not less than 90.0 percent and not more than 120.0 percent of the labeled amount of $C_{11}H_{12}Cl_2N_2O_5$.

Packaging and storage—Preserve in tight containers.

Labeling—Label Tablets to indicate that they are for veterinary use only and are not to be used in animals raised for food production.

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*.

Disintegration ⟨701⟩: 60 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay* under *Chloramphenicol*.

Standard preparation—Transfer about 25 mg of USP Chloramphenicol RS, accurately weighed, to a 200-mL volumetric flask, add 10 mL of water, and heat on a steam bath until completely dissolved. Cool to room temperature, dilute with *Mobile phase* to volume, and mix. Filter a portion of this solution through a 0.5-µm or finer porosity filter, and use the clear filtrate as the *Standard preparation*.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 500 mg of chloramphenicol, to a 200-mL volumetric flask, add 80 mL of water, and heat on a steam bath for 20 minutes, with occasional mixing. Cool to room temperature, dilute with water to volume, and mix. Transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Filter a portion of this solution through a 0.5-µm or finer porosity filter, and use the clear filtrate as the *Assay preparation*.

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 the portion of Tablets taken by the formula:

$$4C(r_U/r_S)$$

in which the terms are as defined therein.

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

We apologize for the inconvenience. The exact auxiliary information for this Documentary Standard is currently unavailable. Please contact Documentary Standards Support (stdsmonographs@usp.org) for assistance during this time.

Chromatographic Database Information: Chromatographic Database

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