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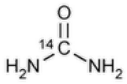
Urea C 14 Capsules



» Urea C 14 Capsules contain $^{14}CH_4N_2O$ in which a portion of the molecules are labeled with radioactive ^{14}C to provide 0.04 MBq (or 1 µCi) of radioactivity per capsule. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{14}C expressed as MBq (or µCi).

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

Expiration date—The expiration date is not later than two years from the date of manufacture.

Labeling—Label it to include the following: the amount of ^{14}C, expressed in MBq (or µCi) per Capsule at the time of calibration; the expiration date; the total radioactivity per container; and the statement, "Caution—Radioactive material."

Radionuclide identification ⟨821⟩—A solution of 1 or more Capsules in 1 N hydrochloric acid when tested using a liquid scintillation counter produces beta emission having a 49 keV mean and a 156 keV max.

Dissolution ⟨711⟩—

Medium: simulated gastric fluid TS; 500 mL.

Apparatus 1: 50 rpm.

Time: 10 minutes.

Procedure—Determine the background levels of ^{14}C with a 1-mL portion of the solution under test using a liquid scintillation counter.

Tolerances: not less than 80% *(Q)* of the labeled amount of ^{14}C is dissolved in 10 minutes.

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

Radionuclidic purity ⟨821⟩—Determine the radionuclidic purity of a solution of 1 or more Capsules in water using a liquid scintillation counter: not less than 99.9% of the radioactivity is present as C 14.

Radiochemical purity—

Adsorbent: 0.25-mm layer of chromatographic cellulose.

Test solution—Open 2 Capsules and place them in a suitable container, add 8 mL of methanol, and mix.

Reference solution: 40 mg of urea per mL, in water.

Application volume: 20 µL of the *Test solution* and 4 µL of the *Reference solution*.

Developing solvent system: n-butanol saturated with water.

Procedure—Proceed as directed for *Thin-Layer Chromatography* under *Chromatography ⟨621⟩*. Locate the spots on the plate by spraying with Ehrlich's reagent. Determine the radioactivity distribution with a suitable radiation detector (see *Radioactivity ⟨821⟩*), and obtain the R_F value: the R_F value of the principal spot from the *Test solution* corresponds to that obtained from the *Reference solution*, and the radioactivity of the ^{14}C band is not less than 90% of the total radioactivity.

Assay for radioactivity ⟨821⟩—Prepare a solution of 1 or more Capsules in 1 N hydrochloric acid. Using a liquid scintillation counter, determine the radioactivity, in MBq (or mCi) per mL by use of a calibrated system.

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

Topic/Question	Contact	Expert Committee
UREA C 14 CAPSULES	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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