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Urea C 13 for Oral Solution

DEFINITION

Urea C 13 for Oral Solution is a dry powder prepared from Urea C 13. It contains NLT 90.0% and NMT 110.0% of the labeled amount of urea C 13 ($^{13}CH_4N_2O$). It contains no preservatives.

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, methanol, and water (89:10:1)

System suitability solution: 2.5 mg/mL of urea and 0.003 mg/mL of biuret in *Mobile phase*

Standard solution: 2 mg/mL of USP Urea C 13 RS in *Mobile phase*

Sample solution: 2 mg/mL of urea C 13 from a portion of Urea C 13 for Oral Solution in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 200 nm

Column: 4.6-mm × 25-cm; 5-µm packing L8

Flow rate: 0.8 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between urea and biuret, *System suitability solution*

Relative standard deviation: NMT 1%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Measure the areas for the major peaks.

Calculate the percentage of the labeled amount of urea C 13 ($^{13}CH_4N_2O$) in the portion of Urea C 13 for Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Urea C 13 RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of urea C 13 in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩**

Acceptance criteria

Total aerobic microbial count: NMT 10^3 cfu/g

Yeast count: NMT 10^2 cfu/g

***Salmonella* species** and ***Escherichia coli*:** Absent

• **Completeness of Solution ⟨641⟩**

Sample solution: Nominally 100 mg/mL of urea C 13 from a portion of Urea C 13 for Oral Solution in carbon dioxide-free water

Acceptance criteria: Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in sterile, well-closed containers. Store at 15°–30°.

• **Labeling:** Label it to indicate that the solution is to be discarded if particulate matter is visible after reconstitution. [Note—It is to be reconstituted with sterile purified water.]

• **USP Reference Standards** ⟨11⟩

USP Urea C 13 RS

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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