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Urea Compounded Irrigation

DEFINITION

Urea Compounded Irrigation contains NLT 90.0% and NMT 110.0% of the labeled amount of urea (CH_4N_2O).

Prepare Urea Compounded Irrigation 200 mg/mL (20%) as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Urea	10 g
Sodium Chloride Irrigation (0.9%), a sufficient quantity to make	50 mL

Dissolve the *Urea* in *Sodium Chloride Irrigation*. Pass through a sterilizing filter of 0.22-µm pore size into a sterile single-dose plastic bottle. [NOTE—Sterilize through filtration. Urea is not heat stable.]

ASSAY

• **PROCEDURE**

Mobile phase: Water

Standard solution: 0.5 mg/mL of USP Urea RS in water

Sample solution: Transfer 0.25 mL of Irrigation into a 100-mL volumetric flask, and add water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 192 nm

Column: 4.6-mm × 25-cm; 5-µm packing L96

Temperatures

Autosampler: 4°

Column: 25°

Flow rate: 1.0 mL/min

Injection volume: 8 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for urea is about 3.3 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of urea (CH_4N_2O) in the portion of Irrigation taken:

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

r_U = peak response of urea from the *Sample solution*

r_S = peak response of urea from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 6.5–9.0

• **Sterility Tests** ⟨71⟩, *Test for Sterility of the Product to Be Examined, Membrane Filtration***:** It meets the requirements.

• **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 0.003 USP Endotoxin Units/mg

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in sterile, single-dose plastic bottles. Store at controlled room temperature or in a refrigerator.

Change to read:

• **Beyond-Use Date:** ▲In the absence of performing and completing a sterility and endotoxin test, the storage conditions in *Pharmaceutical Compounding – Sterile Preparations* ⟨797⟩, *14.3 Establishing a BUD for a CSP* apply.▲ (CN 1-Nov-2023) When sterility and endotoxin results are within acceptable limits, NMT 60 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator.

• **Labeling:** Label it to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Urea RS

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

Topic/Question	Contact	Expert Committee
UREA COMPOUNDED IRRIGATION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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