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Cytarabine for Injection

DEFINITION
Cytarabine for Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of cytarabine ($C_9H_{13}N_3O_5$).

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**

Solution A: 0.73 g/L of monobasic sodium phosphate and 1.4 g/L of dibasic sodium phosphate in water

Mobile phase: Methanol and *Solution A* (5:95)

Standard solution: 0.1 mg/mL of USP Cytarabine RS in water

System suitability solution: 0.1 mg/mL each of USP Uracil Arabinoside RS and USP Cytarabine RS in water prepared as follows. Dissolve USP Uracil Arabinoside RS in *Standard solution*.

Sample solution: 0.1 mg/mL of cytarabine in water prepared as follows. Separately constitute 5 vials of Cytarabine for Injection in a volume of water corresponding to the volume specified in the labeling. Pool and mix the constituted solutions in a suitable container. Transfer a volume of the constituted solution, nominally equivalent to 100 mg of cytarabine, into a 100-mL volumetric flask, and dilute with water to volume. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1.0 mL/min

Injection volume: 10 µL

After chromatography has been completed, flush the column with a mixture of water and methanol (7:3).

System suitability

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

[Note—The relative retention times for cytarabine and uracil arabinoside are about 1.0 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 2.5 between cytarabine and uracil arabinoside, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cytarabine ($C_9H_{13}N_3O_5$) in the portion of Cytarabine for Injection 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 Cytarabine RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

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

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: 10 mg/mL of cytarabine

Acceptance criteria: 4.0–6.0

• **Water Determination, *Method I*⟨921⟩:** NMT 3.0%

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.07 USP Endotoxin Unit/mg of cytarabine.

• **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Other Requirements:** The drug substance in the vial meets the requirements for *Cytarabine*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*.

• **Labeling:** It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

• **USP Reference Standards ⟨11⟩**

USP Cytarabine RS

USP Uracil Arabinoside RS

2,4(1*H*,3*H*)-Pyrimidinedione, 1-beta-D-arabinofuranosyl-.

$C_9H_{12}N_2O_6$ 244.20

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

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

Chromatographic Database Information: Chromatographic Database

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