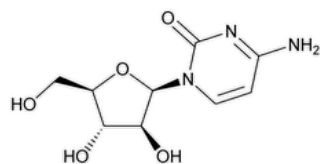


Status: Currently Official on 14-Feb-2025  
 Official Date: Official as of 01-May-2020  
 Document Type: USP Monographs  
 DocId: GUID-AE23EDFB-4FDA-489E-8F9B-C26C800B5237\_5\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M21810\\_05\\_01](https://doi.org/10.31003/USPNF_M21810_05_01)  
 DOI Ref: 8kza6

© 2025 USPC  
 Do not distribute

# Cytarabine



$C_9H_{13}N_3O_5$  243.22

2(1*H*)-Pyrimidinone, 4-amino-1-β-D-arabinofuranosyl-;

1-β-D-Arabinofuranosylcytosine CAS RN®: 147-94-4.

## DEFINITION

Cytarabine contains NLT 98.0% and NMT 102.0% of cytarabine ( $C_9H_{13}N_3O_5$ ), calculated on the dried basis.

### Change to read:

## IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197M▲ (CN 1-May-2020)
- **B.** 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

### 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

[NOTE—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 0.73%, *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 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)

$C_U$  = concentration of Cytarabine in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the dried basis

#### IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

• **ORGANIC IMPURITIES**

**Buffer A:** 0.02 M [monobasic sodium phosphate](#) in [water](#)

**Buffer B:** 0.02 M [dibasic sodium phosphate](#) in [water](#)

**Buffer:** Buffer A and Buffer B (1:1). Adjust with 0.1 M [sodium hydroxide](#) or 0.1 M [phosphoric acid](#) to a pH of 7.0.

**Solution A:** [Methanol](#) and Buffer (2:98)

**Solution B:** [Methanol](#) and Buffer (30:70)

**Mobile phase:** See [Table 1](#).

**Table 1**

| Time<br>(min) | Solution A<br>(%) | Solution B<br>(%) |
|---------------|-------------------|-------------------|
| 0             | 100               | 0                 |
| 10            | 100               | 0                 |
| 20            | 0                 | 100               |
| 25            | 0                 | 100               |
| 30            | 100               | 0                 |
| 50            | 100               | 0                 |

**System suitability solution:** 0.02 mg/mL of [USP Uridine RS](#), 0.02 mg/mL of [USP Uracil Arabinoside RS](#), and 5.0 mg/mL of [USP Cytarabine RS](#) in [water](#)

**Standard solution:** 4 µg/mL of [USP Cytarabine RS](#) in [water](#)

**Sample solution:** 5 mg/mL of Cytarabine in water. Prepare this solution fresh daily.

#### Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 25-cm; packing [L1](#)

**Flow rate:** 1 mL/min

**Injection volume:** 20 µL

#### System suitability

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

#### Suitability requirements

**Resolution:** NLT 1.25 between cytarabine and uridine, *System suitability solution*

**Relative standard deviation:** NMT 3.0%, *Standard solution*

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Cytarabine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$