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# Didanosine for Oral Solution

## DEFINITION

Didanosine for Oral Solution, when reconstituted as directed in the labeling, yields a 10 mg/mL solution that contains NLT 90.0% and NMT 110.0% of the labeled amount of didanosine ($C_{10}H_{12}N_4O_3$).

## IDENTIFICATION

***Change to read:***

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

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

## ASSAY

***Change to read:***

• **Procedure**

**Solution A:** 0.77 mg/mL of ammonium acetate in water

**Mobile phase:** Acetonitrile and *Solution A* (1:24)

**Standard solution:** 0.1 mg/mL of USP Didanosine RS in water. [Note—Use this solution within 24 h of preparation.]

**Sample solution:** 0.1 mg/mL obtained by diluting the contents of 1 bottle of Didanosine for Oral Solution in water. [Note—Use this solution within 24 h of preparation.]

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 254 nm

**Analytical column:** 4-mm × 25-cm; packing L1

**Guard column:** 4.6-mm × ▲20-mm;▲ (ERR 1-May-2018) packing L1

**Flow rate:** 2 mL/min

**Injection size:** 20 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Retention time:** Between 7 and 11 min

**Column efficiency:** NLT 6000 theoretical plates

**Relative standard deviation:** NMT 1.5%

**Analysis**

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

Calculate the percentage of $C_{10}H_{12}N_4O_3$ in the portion of Oral Solution taken:

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

$r_U$ = peak response of the *Sample solution*

$r_S$ = peak response of the *Standard solution*

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

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

**Acceptance criteria:** 90.0%–110.0%

## PERFORMANCE TESTS

• **Deliverable Volume ⟨698⟩:** Meets the requirements

## IMPURITIES

**Organic Impurities**

• **Procedure**

**Solution A, Mobile phase, Sample solution, Chromatographic system,** and **System suitability:** Proceed as directed in the *Assay*.

**Standard solution:** 5 µg/mL of USP Didanosine Related Compound A RS in water

[Note—Use this solution within 48 h of preparation.]

**Analysis**

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

Calculate the percentage of didanosine related compound A in the portion of Oral Solution taken:

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

$r_U$ = peak response of didanosine related compound A from the *Sample solution*

$r_S$ = peak response of didanosine related compound A from the *Standard solution*

$C_S$ = concentration of USP Didanosine Related Compound A RS in the *Standard solution* (mg/mL)

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

**Acceptance criteria:** NMT 1%

## SPECIFIC TESTS

• **Water Determination,** *Method Ia*⟨921⟩**:** NMT 3%

## ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store between 15° and 30°.

• **Labeling:** The label contains directions for constitution of the powder and states the equivalent amount of $C_{10}H_{12}N_4O_3$ in a given volume of Oral Solution obtained after constitution.

• **USP Reference Standards** ⟨11⟩

USP Didanosine RS

USP Didanosine Related Compound A RS

Hypoxanthine

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| DIDANOSINE FOR ORAL SOLUTION | Documentary Standards Support | SM12020 Small Molecules 1 |

**Chromatographic Database Information:** Chromatographic Database

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