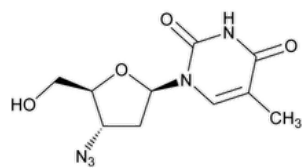


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Zidovudine



$C_{10}H_{13}N_5O_4$ 267.24
Thymidine, 3'-azido-3'-deoxy-;
3'-Azido-3'-deoxythymidine CAS RN®: 30516-87-1.

DEFINITION
Zidovudine contains NLT 97.0% and NMT 102.0% of zidovudine ($C_{10}H_{13}N_5O_4$), calculated on the anhydrous basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197K
- **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
Change to read:

- **PROCEDURE**
▲ **Buffer:** 2 g/L of [ammonium acetate](#) in [water](#). Adjust with [dilute acetic acid](#) or dilute [ammonium hydroxide](#) (1 in 10) to a pH of 6.8.
Solution A: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Buffer (%)	Solution A (%)
0	95	5
3	95	5
18	85	15
28	30	70
43	30	70
45	95	5

Diluent: [Acetonitrile](#), [methanol](#), and *Buffer* (4:20:76)
Standard solution: 0.2 mg/mL of [USP Zidovudine RS](#) in *Diluent*
Sample solution: 0.2 mg/mL of Zidovudine in *Diluent*
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC

Detector: UV 265 nm**Column:** 4.6-mm × 25-cm; 5-μm packing L1**Flow rate:** 1.5 mL/min**Injection volume:** 20 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 2.0%▲ (USP 1-May-2022)**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of zidovudine ($C_{10}H_{13}N_5O_4$) in the portion of Zidovudine taken:

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

 r_U = peak response of zidovudine from the *Sample solution* r_S = peak response of zidovudine from the *Standard solution* C_S = concentration of [USP Zidovudine RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Zidovudine in the *Sample solution* (mg/mL)**Acceptance criteria:** 97.0%–102.0% on the anhydrous basis**IMPURITIES**

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.25%

Delete the following:▲• **LIMIT OF TRIPHENYLMETHANOL AND OTHER IMPURITIES****Standard solution:** 0.1 mg/mL each of [USP Zidovudine RS](#) and triphenylmethanol in methanol**Sample solution:** 20 mg/mL of Zidovudine in methanol**Chromatographic system**(See [Chromatography \(621\), Thin-Layer Chromatography](#).)**Mode:** TLC**Adsorbent:** 0.25-mm layer of chromatographic silica gel mixture containing a fluorescent indicator having an optimal intensity at 254 nm**Application volume:** 10 μL**Developing solvent system:** Chloroform and methanol (9:1)**Spray reagent:** 5 mg/mL of carbazole in alcohol and sulfuric acid (95:5)

Analysis: Develop the chromatogram until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, and allow the solvent to evaporate. Examine the plate under short-wavelength UV light, and compare the intensities of any secondary spots observed in the chromatogram of the *Sample solution* with those of the principal spot in the chromatogram of the *Standard solution*.

Acceptance criteria 1: No secondary spot from the chromatogram of the *Sample solution* is larger or more intense than the principal spot from the *Standard solution*, and the sum of the intensities of the secondary spots obtained from the *Sample solution* corresponds to NMT 3.0%.

Spray the plate with *Spray reagent*, heat for 10 min at 120°, and compare the intensities of any secondary spots observed in the chromatogram of the *Sample solution* with those of the principal spots in the chromatogram of the *Standard solution*.

Acceptance criteria 2: No spot corresponding to triphenylmethanol (R_F about 2.3 relative to the R_F of zidovudine) is more intense than the corresponding spot from the *Standard solution*. No secondary spot from the chromatogram of the *Sample solution* is larger or more intense than the principal spot obtained from the *Standard solution*. The sum of the intensities of the secondary spots from the *Sample solution* corresponds to NMT 3.0%. ▲ (USP 1-May-2022)

Delete the following:▲• **LIMIT OF ZIDOVUDINE RELATED COMPOUNDS B AND C****Mobile phase, Standard solution, Sample solution, Chromatographic system, and System suitability:** Proceed as directed in the Assay.**Analysis****Sample:** *Sample solution*