Perform a blank determination. Each mL of 0.1 N perchloric acid is equivalent to 26.53 mg of $C_{12}H_{15}N_3O_2S$.
Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES
- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Organic Impurities**
  Standard stock solution: 5 mg/mL of USP Albendazole RS in glacial acetic acid
  Standard solution: 0.05 mg/mL of USP Albendazole RS in glacial acetic acid from *Standard stock solution*
  Sample solution: 10 mg/mL in glacial acetic acid
  Chromatographic system
  (See *Chromatography* ⟨621⟩*, Thin-Layer Chromatography*.)
  Mode: TLC
  Adsorbant: 0.25-mm layer of silica gel mixture
  Application volume: 10 µL
  Developing solvent system: Chloroform, ether, and glacial acetic acid (60:10:10)
  Analysis: Proceed as directed for *Chromatography* ⟨621⟩*, Thin-Layer Chromatography*.
  Samples: *Standard stock solution*, *Standard solution*, and *Sample solution*
  Develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, allow the solvent to evaporate from the plate, and examine the plate under short-wavelength UV light.
  Acceptance criteria: 0.5%; no spot, other than the principal spot of the *Sample solution*, is larger or more intense than the principal spot of the *Standard solution*.

SPECIFIC TESTS
- **Loss on Drying ⟨731⟩**
  Analysis: Dry at 105° for 4 h.
  Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
- **USP Reference Standards ⟨11⟩**
  USP Albendazole RS

Albendazole Oral Suspension

DEFINITION
Albendazole Oral Suspension is Albendazole in an aqueous vehicle. It contains one or more preservatives and dispersing or suspending agents. It contains NLT 90.0% and NMT 110.0% of the labeled amount of albendazole ($C_{12}H_{15}N_3O_2S$).

IDENTIFICATION
- **A. Ultraviolet Absorption ⟨197U⟩**
  Sample stock solution: 1 mg/mL of albendazole from a quantity of Suspension, in a mixture of methanol and hydrochloric acid (99:1). Filter the mixture, if necessary, to obtain a clear solution.
  Sample solution: 0.01 mg/mL of albendazole in 0.1 N sodium hydroxide from *Sample stock solution*
  Acceptance criteria: Meets the requirements

ASSAY
- **Procedure**
  Solution A: Methanol and hydrochloric acid (99:1)
  Solution B: 13.75 g/L of monobasic sodium phosphate
  Mobile phase: Methanol and *Solution B* (60:40)
  Standard stock solution: 1 mg/mL of USP Albendazole RS in *Solution A*
  Standard solution: 100 µg/mL of USP Albendazole RS from *Standard stock solution* in *Mobile phase*
  Sample stock solution: Equivalent to 1 mg/mL of albendazole from a volume of Oral Suspension in *Solution A*
  Sample solution: Nominally 100 µg/mL of albendazole from *Sample stock solution* in *Mobile phase*. [NOTE—Filter, if necessary, to obtain a clear solution.]
  Chromatographic system
  (See *Chromatography* ⟨621⟩*, System Suitability*.)
  Mode: LC
  Detector: UV 308 nm
  Column: 4-mm × 25-cm; packing L1
  Flow rate: 2 mL/min
  Injection volume: 20 µL
  System suitability
  Sample: *Standard solution*
  Suitability requirements
  Column efficiency: NLT 2000 theoretical plates
  Tailing factor: NMT 2.0
  Relative standard deviation: NMT 2.0%
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Calculate the percentage of albendazole ($C_{12}H_{15}N_3O_2S$) in the portion of Oral Suspension 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 Albendazole RS in the *Standard solution* (µg/mL)
C_U = nominal concentration of albendazole in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS
- **pH ⟨791⟩:** 4.5–5.5

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
- **Labeling:** Label it to indicate that it is for veterinary use only.
- **USP Reference Standards ⟨11⟩**
  USP Albendazole RS

Albendazole Tablets

» Albendazole Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of albendazole ($C_{12}H_{15}N_3O_2S$).

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

Labeling—Tablets intended for veterinary use only are so labeled.

USP Reference standards ⟨11⟩—
USP Albendazole RS
USP Parbendazole RS

Identification—

A: *Ultraviolet Absorption* ⟨197U⟩—

Solution: Dilute a portion of the clear filtrate used to prepare the *Assay preparation* and a portion of the stock solution used to prepare the *Standard preparation* prepared in the *Assay* with *Acidified methanol,* prepared as directed for *Dissolution,* to obtain solutions containing about 10 µg of albendazole per mL.

B: The retention time of the major peak for albendazole in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Dissolution ⟨711⟩**—**

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Determine the amount of $C_{12}H_{15}N_3O_2S$ dissolved using the following procedure.

Acidified methanol—To about 50 mL of methanol in a 100-mL volumetric flask add 2 mL of hydrochloric acid, dilute with methanol to volume, and mix.

Standard solution—Transfer about 90 mg of USP Albendazole RS, accurately weighed, to a 250-mL volumetric flask, add 10 mL of *Acidified methanol,* and shake to dissolve. Dilute with 0.1 N hydrochloric acid to volume, and mix. Transfer 5.0 mL of this solution to a 200-mL volumetric flask, dilute with 0.1 N sodium hydroxide to volume, and mix.

Procedure—Transfer 10.0 mL of a filtered portion of the solution under test to a 250-mL volumetric flask, dilute with 0.1 N sodium hydroxide to volume, and mix. Concomitantly determine the absorbances of this solution and the *Standard solution* at the wavelengths of maximum and minimum absorbance at about 308 nm and 350 nm, using 0.1 N sodium hydroxide as the blank. Calculate the quantity, in mg, of $C_{12}H_{15}N_3O_2S$ dissolved by the formula:

$$22.5C(A_U / A_S)$$

in which C is the concentration, in µg per mL, of USP Albendazole RS in the *Standard solution;* and A_U and A_S are the differences in absorbance between 308 nm and 350 nm obtained from the solution under test and the *Standard solution,* respectively.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{12}H_{15}N_3O_2S$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩**:** meet the requirements.

Procedure for content uniformity—

Acidified methanol and *Standard solution*—Prepare as directed under *Dissolution.*

Test solution—Place 1 Tablet in a 500-mL volumetric flask, add about 300 mL of *Acidified methanol,* and shake by mechanical means for about 30 minutes. Dilute with *Acidified methanol* to volume, and mix. Filter a portion of this solution, discarding the first 20 mL of the filtrate. Transfer 4.0 mL of the clear filtrate to a 200-mL volumetric flask, dilute with 0.1 N sodium hydroxide to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard solution* and the *Test solution* at the wavelengths of maximum and minimum absorbance at about 308 nm and 350 nm, using 0.1 N sodium hydroxide as the blank. Calculate the quantity, in mg, of $C_{12}H_{15}N_3O_2S$ in the Tablet taken by the formula:

$$25C(A_U / A_S)$$

in which C is the concentration, in µg per mL, of USP Albendazole RS in the Standard preparation; and A_U and A_S are the differences in absorbance between 308 nm and 350 nm obtained from the *Test solution* and the *Standard solution,* respectively.

Assay—

Mobile phase—Dissolve 0.50 g of monobasic ammonium phosphate in 400 mL of water. Add 600 mL of methanol, mix, and filter, discarding the first 15 mL of the filtrate. Degas the clear filtrate before use. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Sulfuric acid in methanol—Prepare a mixture of 1 mL of sulfuric acid and 99 mL of methanol.

Internal standard solution—Transfer about 150 mg of USP Parbendazole RS to a 50-mL volumetric flask. Add 5 mL of *Sulfuric acid in methanol,* 25 mL of methanol, and shake to dissolve. Dilute with methanol to volume, and mix.

Standard preparation—Transfer about 100 mg of USP Albendazole RS, accurately weighed, to a 50-mL volumetric flask. Add 5 mL of *Sulfuric acid in methanol* and 25 mL of methanol, and shake to dissolve. Dilute with methanol to volume, and mix. Transfer 5.0 mL of this stock solution and 5.0 mL of *Internal standard solution* to a second 50-mL volumetric flask, dilute with methanol to volume, and mix.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of albendazole, to a 50-mL volumetric flask. Add 5 mL of *Sulfuric acid in methanol* and 20 mL of methanol, and shake by mechanical means for about 15 minutes. Dilute with methanol to volume, mix, and filter, discarding the first 15 mL of the filtrate. Transfer 5.0 mL of the clear filtrate and 5.0 mL of *Internal standard solution* to a second 50-mL volumetric flask, dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2.0; the column efficiency is not less than 1000 theoretical plates; the resolution between the albendazole peak and the parbendazole peak is not less than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—[NOTE—Use peak heights where peak responses are indicated.] Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{12}H_{15}N_3O_2S$ in the portion of Tablets taken by the formula:

$$500C(R_U / R_S)$$

in which C is the concentration, in mg per mL, of USP Albendazole RS in the *Standard preparation;* and R_U and R_S are the peak response ratios of the albendazole peak to the parbendazole peak obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Albumin Human

DEFINITION

Albumin Human conforms to the regulations of the federal Food and Drug Administration concerning biologics (640.80 to 640.86) (see *Biologics* ⟨1041⟩). It is a sterile, nonpyrogenic preparation of serum albumin obtained by fractionating material (source blood, plasma, serum, or placentas) from healthy human donors, the source material being tested for the absence of hepatitis B surface antigen. It is made by a process that yields a product that is safe for intravenous use. NLT 96% of its total protein is albumin. It is a solution containing, in each 100 mL, either 25 g of serum albumin osmotically equivalent to 500 mL of normal human plasma, or 20 g equivalent to 400 mL, or 5 g equivalent to 100 mL, or 4 g equivalent to 80 mL, and contains NLT 93.75% and NMT 106.25% of the labeled amount in the case of the solution containing 4 g in each 100 mL, and NLT 94.0% and NMT 106.0% of the labeled amount in the other cases. It contains no added antimicrobial agent, but may contain sodium acetyltryptophanate with or without sodium caprylate as a stabilizing agent. It has a sodium content of NLT 130