Identification—

A: *Infrared Absorption* ⟨197M⟩.

B: The R_F value of the principal spot obser ved in the chromatogram of the test solution corresponds to that of the principal spot obser ved in the chromatogram of the *Standard solution*, as obtained in the test for *Chromatographic purity.*

Loss on drying ⟨731⟩**—**Dry it at 105 ° for 4 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.2%.

Chromatographic purity—Dissolve 50 mg of it in 3.0 mL of glacial acetic acid in a 5-mL volumetric flask, dilute with glacial acetic acid to volume, and mix. Similarly prepare a *Standard solution* containing 5 mg of USP Albendazole RS per mL. Transfer 1.0 mL of the *Standard solution* to a 100-mL volumetric flask, dilute with glacial acetic acid to volume, and mix (diluted *Standard solution*). Apply 10-µL portions of the test solution, the *Standard solution*, and the diluted *Standard solution* to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩), coated with a 0.25-mm layer of silica gel mixture, and allow the spots to dr y. Develop the chromatogram in a solvent system consisting of a mixture of chloroform, glacial acetic acid, and ether (60:10:10) 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: no spot, other than the principal spot, in the chromatogram of the test solution is larger or more intense than the principal spot in the chromatogram of the diluted *Standard solution* (0.5%).

Assay—Transfer about 250 mg of Albendazole, accurately weighed, to a suitable flask, and dissolve in 100 mL of glacial acetic acid, warming gently if necessar y. Cool, and titrate with 0.1 N perchloric acid VS to a potentiometric endpoint (see *Titrimetry* ⟨541⟩. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N per chloric acid is equivalent to 26.53 mg of $C_{12}H_{15}N_3O_2S$.

Albendazole Oral Suspension

» Albendazole Oral Suspension is Albendazole in an aqueous vehicle. It contains one or more preservatives and dispersing or suspending agents. It contains not less than 90.0 per cent and not more than 110.0 per cent 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—Label it to indicate that it is for veterinar y use only.

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

Identification, *Ultraviolet Absorption* ⟨197U⟩**—**

Solution—Dilute a quantity of Suspension with a mixture of methanol and hydrochloric acid (99:1) to obtain a solution having a concentration of about 1 mg per mL. Filter the mixture, if necessary, to obtain a clear solution. T ransfer 1 mL of this solution to a 100-mL volumetric flask, dilute with 0.1 N sodium hydroxide to volume, and mix.

pH ⟨791⟩**:** between 4.5 and 5.5.

Assay—

Acidified methanol—Use a mixture of methanol and hydrochloric acid (99:1).

Mobile phase—Dissolve 11.0 g of monobasic sodium phosphate in 800 mL of water. Add 1200 mL of methanol, and mix. Make adjustments if necessar y (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Quantitatively dissolve an accurately weighed quantity of USP Albendazole RS in *Acidified methanol* to obtain a stock solution having a known concentration of about 1 mg per mL. Dilute an accurately measured volume of this stock solution with *Mobile phase* to obtain a solution having a known concentration of about 100 µg per mL.

Assay preparation—Transfer an accurately measured volume of Oral Suspension, equivalent to about 100 mg of albendazole, to a 100-mL volumetric flask, dilute with *Acidified methanol* to volume, and mix. T ransfer 10.0 mL of this solution to a second 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Filter, if necessar y, to obtain a clear solution.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 308-nm detector and a 4-mm × 25-cm column that contains 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 column efficiency is not less than 2000 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—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 albendazole ($C_{12}H_{15}N_3O_2S$) in each mL of the Oral Suspension taken by the formula:

$$(C/V)(r_U / r_S)$$

in which C is the concentration, in µg per mL, of USP Albendazole RS in the *Standard preparation; V* is the volume, in mL, of Oral Suspension taken to prepare the *Assay preparation;* and r_U and r_S are the albendazole peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Albendazole Tablets

» Albendazole Tablets contain not less than 90.0 percent and not more than 110.0 per cent 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 veterinar y 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. T ransfer 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. T ransfer 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 necessar y (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. T ransfer 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 T ablets 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

» 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 (sour ce blood, plasma, serum, or placentas) from healthy human donors, the source material being tested for the absence of hepatitis B sur face antigen. It is made by a process that yields a product that is safe for intravenous use. Not less than 96 per cent 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 thereof, and contains not less than 93.75 percent and not more than 106.25 per cent of the labeled amount in the case of the solution containing 4 g in each 100 mL, and not less than 94.0 percent and not more than 106.0 per cent 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 not less than 130 mEq per L and not more than 160 mEq per L. It has a heme content such that the absorbance of a so-