Perform a blank determination. Each mL of 0.1 N perchloric acid is equivalent to 26.53 mg of C\textsubscript{12}H\textsubscript{15}N\textsubscript{3}O\textsubscript{2}S. 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
  - Sample 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
- **Apparatus:** 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°C 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

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**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\textsubscript{12}H\textsubscript{15}N\textsubscript{3}O\textsubscript{2}S).

**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\textsubscript{12}H\textsubscript{15}N\textsubscript{3}O\textsubscript{2}S) in the portion of Oral Suspension taken:

\[
\text{Result} = \left(\frac{r_U}{r_S}\right) \times \left(\frac{C_S}{C_U}\right) \times 100
\]

\[
C_U = \text{nominal concentration of albendazole in the Sample solution (µg/mL)}
\]

**Specifications**
- **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

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**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\textsubscript{12}H\textsubscript{15}N\textsubscript{3}O\textsubscript{2}S).

**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.
**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 50 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 µg per mL.