Albendazole Tablets

Albendazole Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of albendazole (C₁₂H₁₅N₃O₂S).

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
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 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 C₁₂H₁₅N₃O₂S dissolved using the following procedure.

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 (C₁₂H₁₅N₃O₂S).

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

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. Transfer 1 mL of this solution to a 100-mL volumetric flask, dilute with 0.1 N sodium hydroxide to volume, and mix.

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 necessary. 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 perchloric acid is equivalent to 2.53 mg of C₁₂H₁₅N₃O₂S.

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. Transfer 10.0 mL of this solution to a second 100-mL volumetric flask, dilute with Mobile phase to volume, and mix. Filter, if necessary, to obtain a clear solution.

Chromatographic system (see Chromatography (621))—The liquid chromatograph is equipped with a 308-nm detector and a 4-mm x 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 (C₁₂H₁₅N₃O₂S) in each mL of the Oral Suspension taken by the formula:

\[ \frac{C}{V} = \frac{r_U}{r_S} \]

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.

Identification—
A: Infrared Absorption (197M).

B: The Rf value of the principal spot observed in the chromatogram of the Assay preparation is 0.65 ± 0.05. Each mL of 0.1 N perchloric acid is equivalent to 2.53 mg of C₁₂H₁₅N₃O₂S.

Loss on drying (731)—Dry it at 105 °C 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 dry. 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 necessary. 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 perchloric acid is equivalent to 26.53 mg of C₁₂H₁₅N₃O₂S.

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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 necessary. 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 perchloric acid is equivalent to 26.53 mg of C₁₂H₁₅N₃O₂S.
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 solu-
tion under test to a 250-mL volumetric flask, dilute with 0.1 N
sodium hydroxide to volume, and mix. Concomitantly deter-
mine 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 C₁₂H₁₅N₃O₂S dissolved
by the formula:

\[ \frac{22.5C(A₀ / A₁)}{A₀ - A₁} \]

in which \( C \) is the concentration, in \( \mu g \) per mL, of USP Al-
 bendazole RS in the Standard solution; and \( A₀ \) and \( A₁ \) are the
differences in absorbance between 308 nm and 350 nm ob-
tained from the solution under test and the Standard solution,
respectively.

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 mechani-
cal 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 fil-
trate 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 C₁₂H₁₅N₃O₂S in the Tablet taken by the
formula:

\[ \frac{25C(A₀ / A₁)}{A₀ - A₁} \]

in which \( C \) is the concentration, in \( \mu g \) per mL, of USP Al-
 bendazole RS in the Standard preparation; and \( A₀ \) and \( A₁ \) are the
differences in absorbance between 308 nm and 350 nm ob-
tained 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 Sys-
tem Suitability under Chromatography (621)).

Sulfuric acid in methanol—Prepare a mixture of 1 mL of sulfu-
ric 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 Sul-
furic acid in methanol, 25 mL of methanol, and shake to dis-
solve. Dilute with methanol to volume, and mix.

Standard preparation—Transfer about 100 mg of USP Al-
bendazole 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 pow-
der, 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, dis-
carding 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 sec-
don 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 Stan-
dard 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 repli-
cate 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
C₁₂H₁₅N₃O₂S in the portion of Tablets taken by the formula:

\[ 500C(R₆ / R₇) \]

in which \( C \) is the concentration, in mg per mL, of USP Al-
 bendazole RS in the Standard preparation; and \( R₆ \) and \( R₇ \) are the
peak response ratios of the albendazole peak to the par-
bendazole 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 con-
cerning biologics (640.80 to 640.86) (see Bi-
ologics (1041)). It is a sterile, nonpyrogenic prepa-
rati on of serum albumin obtained by fractionating material (source blood, plasma, se-
rum, 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 intra-
venous 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 os-
motically 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 percent 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 percent of
the labeled amount in the other cases. It con-
tains no added antimicrobial agent, but may con-
tain 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-