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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 ($C_{12}H_{15}N_3O_2S$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

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

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ALBENDAZOLE ORAL SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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