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Ethambutol Hydrochloride Compounded Oral Suspension

DEFINITION

Ethambutol Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of ethambutol hydrochloride ($C_{10}H_{24}N_2O_2 \cdot 2HCl$).

Prepare Ethambutol Hydrochloride Compounded Oral Suspension 100 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Ethambutol Hydrochloride tablets[a] equivalent to	3 g of ethambutol hydrochloride
Vehicle: a 1:1 mixture of Ora-Plus[b] and Ora-Sweet SF[b], a sufficient quantity to make	30 mL

[a] Ethambutol Hydrochloride 100-mg tablet(s), Lupin Pharmaceuticals, Baltimore, MD.

[b] Perrigo Laboratories, Allegan, MI.

Place the required number of tablets in a suitable container and comminute to a fine powder. Wet the powder with a small amount of *Vehicle* and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: 0.1% triethylamine in water, adjusted with phosphoric acid to a pH of 7.0. Pass through a nylon filter of 0.45-µm pore size and degas.

Mobile phase: Acetonitrile and *Solution A* (50:50)

Diluent: 1.4 g/L of sodium phosphate in water adjusted with phosphoric acid to a pH of 6.8

Standard stock solution: 10 mg/mL of USP Ethambutol Hydrochloride RS in *Diluent*. Sonicate to mix well. Store at 2°–8°.

Standard solution: Transfer 0.25 mL of the *Standard stock solution* to a 5-mL volumetric flask, dilute with *Diluent* to volume, and mix well. Transfer an aliquot to a centrifuge tube, and centrifuge for 5 min at 14,000 rpm at 2°–8°. Transfer the supernatant to an amber vial and store at 2°–8°.

Sample solution: Transfer 2 mL of Oral Suspension to a 20-mL volumetric flask, dilute with *Diluent* to volume, and sonicate to mix well. Transfer 0.25 mL of the resultant solution to a 5-mL volumetric flask, dilute with *Diluent* to volume, and mix well. Transfer an aliquot to a centrifuge tube, and centrifuge for 5 min at 14,000 rpm at 2°–8°. Transfer the supernatant to an amber vial and store at 2°–8°.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV-Vis 200 nm

Column: 4.6-mm × 25-cm; 5-µm packing L10

Temperatures

Autosampler: 5°

Column: 30°

Flow rate: 1.3 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for ethambutol hydrochloride is about 3.7 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ethambutol hydrochloride ($C_{10}H_{24}N_2O_2 \cdot 2HCl$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of ethambutol hydrochloride from the *Sample solution*

r_S = peak response of ethambutol hydrochloride from the *Standard solution*

C_S = concentration of USP Ethambutol Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of ethambutol hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.5–5.6

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant plastic containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Ethambutol Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
ETHAMBUTOL HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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