

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](#)**Most Recently Appeared In:**

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