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Erythromycin Ethylsuccinate for Oral Suspension

» Erythromycin Ethylsuccinate for Oral Suspension is a dry mixture of Erythromycin Ethylsuccinate with one or more suitable buffers, colors, diluents, dispersants, and flavors. It contains the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of erythromycin ($C_{37}H_{67}NO_{13}$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Erythromycin RS
USP Erythromycin Ethylsuccinate RS

Change to read:

Identification—To a quantity of Erythromycin Ethylsuccinate for Oral Suspension add a volume of methanol sufficient to yield a solution containing the equivalent of about 2.5 mg of erythromycin per mL, and stir for 30 minutes. Centrifuge a portion of this mixture, and use the clear supernatant as the test solution. ▲Prepare a Standard solution of USP Erythromycin Ethylsuccinate RS in methanol containing about 3 mg per mL. Apply separately 10 µL each of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture, and allow to dry. Place the plate in an unlined chromatographic chamber, and develop the chromatograms in a solvent system consisting of a mixture of methanol and chloroform (85:15) until the solvent front has moved about 9 cm. Remove the plate from the chamber, mark the solvent front, and allow the solvent to evaporate. Spray the plate with a mixture of dehydrated alcohol, *p*-methoxybenzaldehyde, and sulfuric acid (90:5:5). Heat the plate at 100° for 10 minutes, and examine the chromatograms, in which the erythromycin and succinic acid moieties appear as black-to-purple spots: the R_F values of the principal spots obtained from the test solution correspond to those obtained from the Standard solution.▲ (ERR 1-Apr-2023)

Uniformity of dosage units ⟨905⟩—
FOR SOLID PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩: meets the requirements.

pH ⟨791⟩: between 7.0 and 9.0, in the suspension constituted as directed in the labeling.

Loss on drying ⟨731⟩—Dry about 100 mg in a capillary-stoppered bottle in vacuum at 60° for 3 hours: it loses not more than 1.0% of its weight.

Change to read:

Assay—Constitute Erythromycin Ethylsuccinate for Oral Suspension as directed in the labeling, and proceed as directed ▲for erythromycin under *Antibiotics—Microbial Assays ⟨81⟩*, using an accurately measured volume of the reconstituted suspension, freshly mixed and free from air bubbles, blended for 4 ± 1 minutes in a high-speed glass blender jar with sufficient methanol to give a stock solution containing the equivalent of about 1 mg of erythromycin per mL. Dilute this stock solution quantitatively with *Buffer B.3* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.▲ (ERR 1-Apr-2023)

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

Topic/Question	Contact	Expert Committee
ERYTHROMYCIN ETHYLSUCCINATE FOR ORAL SUSPENSION	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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