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Erythromycin and Benzoyl Peroxide Topical Gel

» Erythromycin and Benzoyl Peroxide Topical Gel is a mixture of Erythromycin in a suitable gel vehicle containing benzoyl peroxide and one or more suitable dispersants, stabilizers, and wetting agents. It contains not less than 90.0 percent and not more than 125.0 percent of the labeled amounts of erythromycin ($C_{37}H_{67}NO_{13}$) and benzoyl peroxide ($C_{14}H_{10}O_4$).

Packaging and storage—Before mixing, preserve the Erythromycin and the vehicle containing benzoyl peroxide in separate, tight containers. After mixing, preserve the mixture in tight containers.

USP Reference standards ⟨11⟩—

USP Erythromycin RS

Identification—Prepare *Standard preparation* and an *Assay preparation* as directed in the *Assay,* except to omit the *Internal standard solution*, and chromatograph as directed in the *Assay:* the *Assay preparation* exhibits a major peak for benzoyl peroxide, the retention time of which corresponds to that exhibited by the *Standard preparation*.

Minimum fill ⟨755⟩: meets the requirements.

Limit of benzoyl peroxide related substances—

Mobile phase A, Mobile phase B, Standard preparation A, Standard preparation B, Standard preparation C, Standard preparation D, Resolution solution, and *Chromatographic system*—Proceed as directed in the test for *Related compounds* under *Benzoyl Peroxide Gel*.

Test preparation—Transfer an accurately weighed quantity of Topical Gel, equivalent to about 100 mg of benzoyl peroxide, to a 50-mL volumetric flask, add 25 mL of acetonitrile, shake vigorously to disperse the specimen, sonicate for 5 minutes, dilute with acetonitrile to volume, mix, and filter.

Procedure—Proceed as directed for *Procedure* in the test for *Related compounds* under *Benzoyl Peroxide Gel:* it meets the limits stated.

Assay for erythromycin—Proceed as directed for erythromycin under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately weighed portion of Topical Gel blended for 3 to 5 minutes in a high-speed glass blender jar containing 0.5 mL of polysorbate 80 and an accurately measured volume of *Buffer B.3* sufficient to obtain a stock solution having a convenient concentration of erythromycin. Dilute an accurately measured volume of this stock solution quantitatively with *Buffer B.3* to obtain a *Test Dilution* having a concentration of erythromycin assumed to be equal to the median dose level of the Standard.

Assay for benzoyl peroxide—

Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Benzoyl Peroxide Gel*.

Assay preparation—Prepare as directed for *Assay preparation* in the *Assay* under *Benzoyl Peroxide Gel*, using Topical Gel.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Benzoyl Peroxide Gel*. Calculate the quantity, in mg, of benzoyl peroxide ($C_{14}H_{10}O_4$) in the portion of Topical Gel taken by the formula:

$$125C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of benzoyl peroxide in the *Standard preparation*, and R_U and R_S are the ratios of benzoyl peroxide peak response to ethyl benzoate peak response obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
ERYTHROMYCIN AND BENZOYL PEROXIDE TOPICAL GEL	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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