

Draft Guidance on Nicotine Polacrilex

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Nicotine polacrilex

Dosage Form; Route: Troche/lozenge; oral

Recommended Studies: One study

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: Eq. 4 mg (base)
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: None

Analytes to measure (in appropriate biological fluid): Nicotine in plasma

Bioequivalence based on (90% CI): Nicotine

Waiver request of in-vivo testing: Eq. 2 mg based on (i) acceptable bioequivalence study on the Eq. 4 mg base strength, (ii) acceptable in-vitro dissolution testing on all strengths, and (iii) proportional similarity of the formulation across all strengths. Please refer to the Mirtazapine Tablet Guidance for additional information regarding waivers of in-vivo testing.

Lozenges with alternate flavors can not be filed in the same ANDA as the mint flavored lozenge. For each flavor, a separate submission (ANDA) should be submitted.

Lozenges with an alternate flavor may be eligible for a waiver of the bioequivalence study requirements based on (1) an acceptable bioequivalence study on the 4 mg strength of the mint lozenge, (2) acceptable dissolution testing for the nicotine polacrilex lozenge with additional flavor vs. the RLD, (3) proportional similarity in the formulations of the nicotine polacrilex lozenge with additional flavor and nicotine polacrilex lozenge with mint flavor, and (4) the additional flavor (the inactives) has been approved for the same route of administration.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).