

Contains Nonbinding Recommendations

Draft Guidance on Chlorpheniramine Polistirex; Hydrocodone Polistirex

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredients: Chlorpheniramine Polistirex; Hydrocodone Polistirex

Form/Route: Extended Release Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: Eq. to 8 mg maleate; Eq. to 10 mg bitartrate/ 5 mL
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 8 mg/10 mg per 5 mL
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments:

Analytes to measure (in appropriate biological fluid): Chlorpheniramine and hydrocodone in plasma

Bioequivalence based on (90% CI): Chlorpheniramine and hydrocodone

Waiver request of *in-vivo* testing: Not Applicable

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please note that a dosage unit for a suspension is the labeled strength (5 ml). A total of 12 units from 12 different bottles should be used.

For modified release products, dissolution profiles generated using USP Apparatus I at 100 rpm and/or Apparatus II at 50 rpm in at least three dissolution media (pH 1.2, 4.5 and 6.8 buffer) on 12 dosage units each of test and reference products should be submitted in the application. Agitation speeds may have to be increased if appropriate. It is acceptable to add a small amount of surfactant, if necessary. Please include early sampling times of 1, 2, and 4 hours and continue every 2 hours until at least 80% of the drug is released. Specifications will be determined upon review of the data submitted in the application