Contains Nonbinding Recommendations

Draft Guidance on Chlorpromazine Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:	Chlorpromazine hydrochloride
Dosage Form; Route:	Concentrate; oral
Recommended Studies:	Request for waiver of in vivo bioequivalence study requirements according to 21 CFR 320.22 (b) (3)

Analytes to measure (in appropriate biological fluid): Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: 30 mg/mL and 100 mg/mL pursuant to 21CFR 320.22 (b)(3)

Dissolution test method and sampling times: Not applicable