

Draft Guidance on Fosfomycin Tromethamine

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Fosfomycin tromethamine

Dosage Form; Route: For Solution; oral

Recommended Studies: Request for Waiver of In vivo Bioequivalence Study Requirements

Bioequivalence study recommendations:

Pursuant to 21 CFR 320.22(b)(3), a waiver of *in vivo* BE study for Fosfomycin Tromethamine for Oral Solution may be granted.

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

Bioequivalence based on (90% CI): Not applicable

Dissolution test method and sampling times: Not applicable