

Draft Guidance on Macimorelin Acetate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Solution; oral

Strength: EQ 60 mg base/pouch

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

Bioequivalence study recommendations:

To qualify for a waiver of in vivo BE study requirements under 21 CFR 320.22(b)(3), the generic Macimorelin Acetate for Oral Solution products must contain the same active ingredient in the same concentration and dosage form as the Reference Standard (RS) and should not contain an inactive ingredient or other change in formulation from the RS that may significantly affect absorption of the active ingredient and systemic availability for Macimorelin Acetate for Oral Solution.

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

Bioequivalence based on (90% CI): Not applicable

Dissolution test method and sampling times: Not applicable