

Draft Guidance on Morphine Sulfate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:	Morphine sulfate
Dosage Form; Route:	Solution; oral 100 mg/ 5 mL (20 mg/ mL)
Recommended Study:	Request for Waiver of <i>In vivo</i> Bioequivalence Study Requirements

Bioequivalence Study Recommendations:

To qualify for a waiver of the *in vivo* bioequivalence (BE) study requirements under 21 CFR 320.22(b)(3), a generic Morphine Sulfate Oral solution product, 100 mg/5 mL, must have the same active ingredient in the same concentration as the reference listed drug product (RLD).

If a generic product of morphine sulfate solution of 100 mg/5 mL strength is given at a single dose of 333 mg, the difference of inactive ingredient sorbitol between the generic product and RLD should not be greater than 1.6 gram of sorbitol.

All ingredients in the test and reference formulations are to be compared using the same units, either %w/w or %w/v based on the maximum single dose of 333 mg of Morphine sulfate.

In 21 CFR 314.94(a)(9)(v), the regulation specifies that the applicant must identify and characterize any formulation differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.