

Contains Nonbinding Recommendations

Draft – Not for Implementation

**Draft Guidance on Magnesium Sulfate; Polyethylene Glycol 3350; Potassium Chloride;
Sodium Chloride; Sodium Sulfate**

November 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredients:	Magnesium sulfate; Polyethylene glycol 3350; Potassium chloride; Sodium chloride; Sodium sulfate
Dosage Form:	For solution
Route:	Oral
Strength:	0.9 gm/bot; 178.7 gm/bot; 1.12 gm/bot; 0.5 gm/bot; 7.3 gm/bot
Recommended Study:	Request for waiver of in vivo bioequivalence study requirements

To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of magnesium sulfate; polyethylene glycol 3350; potassium chloride; sodium chloride; sodium sulfate for oral solution must contain the same active drug ingredients in the same concentration and dosage form as the reference listed drug and contain no inactive ingredient or other change in formulation from the reference listed drug that may significantly affect local availability for product intended to act locally.

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