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Draft Guidance on Pyridostigmine Bromide

December 2025

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Active Ingredient: Pyridostigmine bromide

Dosage Form: Syrup

Route: Oral

Strength: 60 mg/5 mL

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 pyridostigmine bromide oral syrup must contain the same active drug ingredient 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 systemic availability.

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