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Draft Guidance on Trofinetide

August 2024

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Active Ingredient: Trofinetide

Dosage Form: Solution

Route: Oral

Strength: 200 mg/mL

Recommended Study: Request for waiver of in vivo bioequivalence study requirement

To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of trofinetide oral solution must contain the same active ingredient, in the same concentration and dosage form as the reference listed drug and must not include any inactive ingredients or formulation changes that could significantly affect the absorption of the active ingredient.

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