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Draft Guidance on Maralixibat Chloride

August 2023

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Active Ingredient: Maralixibat chloride

Dosage Form: Solution

Route: Oral

Strength: EQ 9.5 mg Base/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 maralixibat oral solution 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 local availability for product intended to act locally.

Document History: Recommended August 2023

Unique Agency Identifier: PSG_214662