

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Netupitant; Palonosetron Hydrochloride

October 2024

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Active Ingredients: Netupitant; Palonosetron hydrochloride

Dosage Form: Capsule

Route: Oral

Strength: 300 mg; EQ 0.5 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-way crossover or parallel group
Strength: 300 mg; EQ 0.5 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Females of reproductive potential should use effective contraception during the study. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of netupitant and palonosetron. Alternatively, a parallel study design may be considered.

Analytes to measure: Netupitant and palonosetron in plasma

Bioequivalence based on (90% CI): Netupitant and palonosetron

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended September 2015; Revised October 2024

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.