

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

## **Draft Guidance on Pitolisant Hydrochloride**

**May 2021**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

This is a new draft product-specific guidance for industry on generic pitolisant hydrochloride.

**Active Ingredient:** Pitolisant hydrochloride

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period, crossover in vivo  
Strength: EQ 17.8 mg Base  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: Exclude subjects with risk factors for QT interval prolongation and torsade de pointes. Monitor subjects for electrocardiogram changes during the study. Females of reproductive potential should use non-hormonal contraceptive method during the study and for at least 21 days after completion of the study.

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2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period, crossover in vivo

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Strength: EQ 17.8 mg Base  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: See comments above.

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**Analyte to measure:** Pitolisant in serum

**Bioequivalence based on (90% CI):** Pitolisant

**Waiver request of in vivo testing:** EQ 4.45 mg Base based on (i) acceptable bioequivalence studies on the EQ 17.8 mg Base strength, (ii) proportionally similar between both strengths, and (iii) acceptable in vitro dissolution testing of both strengths

**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 both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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