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*Draft – Not for Implementation*

## **Draft Guidance on Pramipexole Dihydrochloride**

**October 2024**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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<b>Active Ingredient:</b>	Pramipexole dihydrochloride
<b>Dosage Form:</b>	Tablet
<b>Route:</b>	Oral
<b>Strengths:</b>	0.125 mg, 0.25 mg, 0.5 mg, 0.75 mg, 1 mg, 1.5 mg
<b>Recommended Studies:</b>	Two options: (1) Biopharmaceutics Classification System (BCS)-based biowaiver or (2) one in vivo bioequivalence study with pharmacokinetic endpoints

### **I. Option 1: BCS Class I-based biowaiver**

A waiver request of in vivo testing for all the strengths of this product may be considered provided that the appropriate documentation regarding high solubility, high permeability and rapid dissolution as detailed in the most recent version of the FDA guidance for industry on *M9 Biopharmaceutics Classification System-Based Biowaivers<sup>a</sup>* is submitted in the application. Applicants may use the information contained in the approved labeling of the reference listed drug (RLD). Peer reviewed articles may not contain the necessary details of the testing for the Agency to make a judgment regarding the quality of the studies. A decision regarding the acceptability of the waiver request can only be made upon assessment of the data submitted in the application.

**I. Option 2: One in vivo bioequivalence study with pharmacokinetic endpoints**

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 0.25 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: Females of reproductive potential should use effective contraception during the study.

**Analyte to measure:** Pramipexole in plasma

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

**Waiver request of in vivo testing:** 0.125 mg, 0.5 mg, 0.75 mg, 1 mg, and 1.5 mg strengths based on (i) acceptable bioequivalence study on the 0.25 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all 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 all strengths of the test product and RLD.<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

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<sup>a</sup> For the most recent version of a guidance, check the FDA guidance website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

<sup>1</sup> 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*.