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*Draft – Not for Implementation*

## **Draft Guidance on Methylprednisolone**

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** 2 mg, 4 mg, 8 mg, 16 mg, 32 mg

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 32 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: None

**Analyte to measure:** Methylprednisolone in plasma

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

**Waiver request of in-vivo testing:** 2 mg, 4 mg, 8 mg, and 16 mg strengths based on (i) acceptable bioequivalence study on the 32 mg strength, (ii) acceptable in vitro dissolution testing of all strengths and (iii) proportional similarity of 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 reference listed drug (RLD).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

If any strength of the tablet product has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per the most recent version of the FDA guidance for industry on *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.<sup>a</sup>

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**Document History:** Recommended February 2010; Revised May 2019, October 2024

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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>.

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<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*.