CONCERTA® (methylphenidate HCl ER)
Methylphenidate HCl Extended-Release (Authorized Generic)
Bioequivalence

SUMMARY

- Methylphenidate HCl Extended-Release (Authorized Generic) tablets, distributed by Patriot Pharmaceuticals, LLC, is an authorized generic of CONCERTA.[1, 2]
- The term "authorized generic" is most commonly used to describe an approved brand name drug that is marketed as a generic product without the brand name on its label.[3]
- The authorized generic product is both bioequivalent and clinically equivalent to CONCERTA; therefore, the products are substitutable.
- As the authorized generic of CONCERTA, bioequivalence testing and rating is not required by the Food and Drug Administration (FDA) for methylphenidate HCl extended-release tablets distributed by Patriot Pharmaceuticals, LLC.

BACKGROUND

Patriot Pharmaceuticals, LLC launched methylphenidate HCl extended-release tablets authorized generic in February 2019. The term "authorized generic" is most commonly used to describe an approved brand name drug that is marketed as a generic product without the brand name on its label.[3] Brand name companies (or their licensees) may market authorized generics under the company's originally approved NDA.[3] Patriot Pharmaceuticals, LLC did not submit an ANDA, rather it filed under the CONCERTA NDA as another distributor.

Since authorized generics are marketed under the brand name's NDA, they are not listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). However, as stated in the preface to the Orange Book, an authorized generic is considered to be therapeutically equivalent to its brand name drug.[3] Since the authorized generic product is both bioequivalent and clinically equivalent to CONCERTA, the products are substitutable.

Bioequivalence Ratings for Generic Products

For a generic drug to be approved by the FDA, an ANDA must be submitted by the manufacturer of the generic drug. Based on this information, the FDA will rate the drug based on a two-letter system.[4] In general, the FDA considers two products bioequivalent if the 90% confidence intervals (CI) of the geometric mean for certain pharmacokinetic parameters (eg. C_{max}, AUC_{0-t}, and $AUC_{0-\infty}$) of the test drug (eg. generic formulation) compared to the reference drug (eg. innovator brand formulation) fall within 80.00% to 125.00%.[5, 6] A generic that is "AA" rated is essentially bioequivalent (has the same absorption into the blood stream) to the branded product (or "reference listed product") and is therefore considered "therapeutically equivalent". A generic that is AB rated (the most common designation for generics) had differences in bioavailability from the branded product that have been resolved to the satisfaction of the FDA. A generic drug that is "B" rated is not considered to be bioequivalent and thus not therapeutically equivalent to the branded product. AB rated generics may be substituted in the pharmacy for the branded product. Additional information about the FDA rating system and information about the rating for specific drugs can be obtained from the Orange Book.[4]

As the authorized generic of CONCERTA, bioequivalence testing and rating is not required by the FDA for methylphenidate HCl extended-release tablets distributed by Patriot Pharmaceuticals, LLC.

LITERATURE SEARCH

A literature search of MEDLINE® (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 12 July 2023.

REFERENCES

1. CONCERTA (methylphenidate HCl) [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-edb60a5a-a794-4ed6-b7ab-758d0aa94194.

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3. *FDA list of authorized generic drugs*. U.S. Food and Drug Administration; July 2021. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm126389.htm. Accessed 18 August 2021.

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5. *Guidance for industry: bioequivalence studies with pharmacokinetic endpoints for drugs submitted under an ANDA*. U.S. Food and Drug Administration; December 2013. https://www.fda.gov/downloads/drugs/guidances/ucm377465.pdf. Accessed 18 August 2021.

6. *Guidance for industry: statistical approaches to establishing bioequivalence*. U.S Food and Drug Administration; January 2001. https://www.fda.gov/downloads/drugs/guidances/ucm070244.pdf. Accessed 18 August 2021.