

## Draft Guidance on Chlorzoxazone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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>   | Chlorzoxazone   |
| <b>Dosage Form; Route:</b>  | Tablet; oral  |
| <b>Recommended Studies:</b> | Chlorzoxazone Tablet is a DESI <sup>1</sup> effective drug for which there are no known or suspected bioequivalence problems. |

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**Analyte to measure (in appropriate biological fluid):** Not applicable

**Bioequivalence based on (90% CI):** Not applicable

**Waiver request of in vivo testing:** 500 mg pursuant to 21 CFR 320.22 (c) provided that the in vitro dissolution profiles of the test product are comparable to those of the reference product.

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

Chlorzoxazone tablets (500 mg) are scored. For additional information on the evaluation of scored tablets, refer to the FDA Guidance on "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation" issued in March 2013 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf>.

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<sup>1</sup> Drug Efficacy Study Implementation