Product-Specific Recommendations for Generic Drug Development

To successfully develop and manufacture a generic drug product, an applicant should consider that their product is expected to be: pharmaceutically equivalent to its reference listed drug (RLD), i.e., to have the same active ingredient, dosage form, strength, and route of administration under the same conditions of use, bioequivalent to the RLD, i.e., to show no significant difference in the rate and extent of absorption of the active pharmaceutical ingredient; and, consequently, therapeutically equivalent, i.e., to be substitutable for the RLD with the expectation that the generic product will have the same safety and efficacy as its reference listed drug.

According 21 CFR 320.24, different types of evidence may be used to establish bioequivalence for pharmaceutically equivalent drug products, including in vivo or in vitro testing, or both. The selection of the method used to demonstrate bioequivalence depends upon the purpose of the study, the analytical methods available, and the nature of the drug product. Under this regulation, applicants must conduct bioequivalence testing using the most accurate, sensitive, and reproducible approach available among those set forth in 21 CFR 320.24. As the initial step for selecting methodology for generic drug product development, applicants are referred to the following draft guidance:

Draft Guidance for Industry on *Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application (ANDA)* (Dec. 2013)

To further facilitate generic drug product availability and to assist generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval, FDA publishes product-specific recommendations describing the Agency's current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference-listed drugs.

These recommendations are published in an incremental manner and listed below in alphabetical order according to RLD's name. The most recently published

recommendations (new and revised) are listed below.

The Agency is seeking feedback and considers comments to the docket on these recommendations. The comments should be submitted to the Division of Dockets Management (DDM) under Docket FDA-2007-D-0369-0015. For electronic comments, refer to the website http://www.regulations.gov OR mail your written comments to DDM (HFA-305), FDA, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please contact the Regulations.gov Help Desk at 1-877-378-5457 (toll free) for assistance regarding submissions.

For additional information on development of generic drug products refer to http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064964.htm

Bioequivalence Recommendations for Specific Products Arranged by Active Ingredient [Total count 1321]

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Newly Added Recommendations - June 2015 (44 New) 4 Revisions updated 6/29/2015

Active Ingredient (link to Specific Guidance)	Type	Route of Administration	Dosage Form	RLD Application Number (link to Orange Book)	Date Recommended
Abacavir sulfate; Dolutegravir sodium; Lamivudine (PDF - 39KB)	Draft	Oral	Tablet	205551	6/2015
Afatinib dimaleate (PDF - 22KB)	Draft	Oral	Tablet	201292	6/2015
Alendronate sodium (PDF - 40KB)	Draft	Oral	Tablet, Effervescent	202344	6/2015
Aspirin (PDF -KB)	Draft	Oral	Capsule	203697	6/2015

Azelastine HCl and fluticasone propionate (PDF - 78KB)	Draft	Nasal	Spray, metered	202236	6/2015
Budesonide; Formoterol fumarate dihydrate (PDF - 100KB)	Draft	Inhalation	Aerosol, metered	021929	6/2015
Calcium carbonate; Famotidine; Magnesium hydroxide (PDF - 23KB)	Draft	Oral	Tablet, Chewable	20958	6/2015
Canagliflozin; Metformin HCl (PDF -24KB)	Draft	Oral	Tablet	204353	6/2015
Cyclophosphamide (PDF - 43KB)	Draft	Oral	Capsule	203856	6/2015
Cyproheptadine HCl (PDF - 37KB)	Draft	Oral	Tablet	087056	6/2015
Dabrafenib mesylate (PDF - 24KB)	Draft	Oral	Capsule	202806	6/2015
Dapagliflozin (PDF - 23KB)	Draft	Oral	Tablet	202293	6/2015
Dexbrompheniramine maleate; pseudoephedrine sulfate (PDF - 42KB)	Draft	Oral	Capsule	78648	6/2015
Dolutegravir sodium (PDF - 39KB)	Draft	Oral	Tablet	204790	6/2015
Donepezil HCl; Memantine HCl (PDF - 48KB)	Draft	Oral	Capsule, Extended Release	206439	6/2015
Doxycycline hyclate (PDF - 42KB)	Draft	Oral	Tablet	205931	6/2015

Droxidopa (PDF -39KB)	Draft	Oral	Capsule	203202	3/2015
Eliglustat tartrate (PDF - 39KB)	Draft	Oral	Capsule	205494	6/2015
Empagliflozin (PDF - 23KB)	Draft	Oral	Tablet	204629	6/2015
Emtricitabine; Tenofovir disoproxil fumarate (PDF - 23KB)	Draft	Oral	Tablet	21752	6/2015
Enzalutamide (PDF - 61KB)	Draft	Oral	Capsule	203415	6/2015
Fentanyl (PDF - 39KB)	Draft	Sublingual	Spray	202788	6/2015
Indomethacin (PDF - 38KB)	Draft	Oral	Capsule	204768	6/2015
Lanthanum carbonate (PDF - 31KB)	Draft	Oral	Powder	204734	6/2015
Levalbuterol tartrate (PDF - 105KB)	Draft	Inhalation	Aerosol, metered	21730	6/2015
Levomilnacipran HCl (PDF - 25KB)	Draft	Oral	Capsule, Extended Release	204168	6/2015
Macitentan (PDF - 91KB)	Draft	Oral	Tablet	204410	6/2015
Methazolamide (PDF - 55KB)	Draft	Oral	Tablet	040062	6/2015
Miglitol (PDF - 70KB)	Draft	Oral	Tablet	020682	6/2015
Naloxegol oxalate (PDF -39KB)	Draft	Oral	Tablet	204760	6/2015
Naproxen sodium	Draft	Oral	Capsule	21920	6/2015

(PDF - 22KB)					
Nitroglycerin (PDF - 39KB)	Draft	Transdermal	Ointment	087355	6/2015
Omeprazole; sodium bicarbonate (PDF - 59KB)	Draft	Oral	Suspension, powder	22283	6/2015
Oxybutynin (PDF - 171KB)	Draft	Transdermal	Film, Extended Release	202211	6/2015
Oxybutynin (PDF - 35KB)	Draft	Transdermal	Gel, metered	202513	6/2015
Oxycodone hydrochloride (PDF - 42KB)	Draft	Oral	Capsule	200534	6/2015
Primaquine phosphate (PDF - 25KB)	Draft	Oral	Tablet	008316	6/2015
Sildenafil citrate (PDF - 42KB)	Draft	Oral	Suspension	203109	6/2015
Simeprevir sodium (PDF - 39KB)	Draft	Oral	Capsule	205123	6/2015
Sofosbuvir (PDF - 23KB)	Draft	Oral	Tablet	204671	6/2015
Tolcapone (PDF - 39KB)	Draft	Oral	Tablet	020697	6/2015
Vemurafenib (PDF - 40KB)	Draft	Oral	Tablet	202429	6/2015
Vismodegib (PDF - 62KB)	Draft	Oral	Capsule	203388	6/2015
Vortioxetine hydrobromide (PDF - 23KB)	Draft	Oral	Tablet	204447	6/2015

Newly Revised Bioequivalence Recommendations Mar. 2015

Active Ingredient (link to Specific Guidance)	Type	Route of Administration	Dosage Form	RLD Application Number (link to Orange Book)	Date Recommended
Cholestyramine (PDF - 168KB) *Revised*	Draft	Oral	Powder	74557 74558	6/2015
Doxycycline Hyclate (PDF- 19KB) *Revised*	Draft	Oral	Tablet, Delayed Release	50795	6/2014
Prasugrel HCl (PDF - 37 KB) *Revised*	Draft	Oral	Tablet	22307	6/2015
Tiagabine HCl (PDF - 39KB) *Revised*	Draft	Oral	Tablet	20646	6/2015

Resources

- Drug-Related Guidances
- Bioequivalence Recommendations for Specific Products (PDF - 80KB) (updated 6/2010)
- Dissolution Methods Database
- Withdrawn CDER Bioequivalence Recommendations (PDF - 49KB) (updated 3/09/2015)

Page Last Updated: 06/29/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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