Therapeutic Equivalence Codes

The following coding system is used for drug products that the FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products. Approved drug products are considered to be therapeutic equivalents when they are pharmaceutical equivalents, have demonstrated bioequivalence, and can be expected to have the same clinical effect and safety profile.[1]

A Codes | Products that are considered to be therapeutically equivalent to other pharmaceutically equivalent products

AA	Products in conventional dosage forms not presenting bioequivalence problems
AB	Products meeting necessary bioequivalence requirements
AB1	Products meeting necessary bioequivalence requirements - used when there is more than one reference listed drug of the same strength under the same heading
AB2	Products meeting necessary bioequivalence requirements - used when there is more than one reference listed drug of the same strength under the same heading
AB3	Products meeting necessary bioequivalence requirements - used when there is more than one reference listed drug of the same strength under the same heading
AB4	Products meeting necessary bioequivalence requirements - used when there is more than one reference listed drug of the same strength under the same heading
AN	Solutions and powders for aerosolization
AO	Injectable oil solutions
AP	Injectable aqueous solutions and, in certain instances, intravenous non-aqueous solutions
AT	Topical products

B Codes | Products requiring further FDA investigation and review to determine therapeutic equivalence

BC	Extended-release dosage forms (capsules, injectables and tablets)
BD	Active ingredients and dosage forms with documented bioequivalence problems
BE	Delayed-release oral dosage forms
BN	Products in aerosol-nebulizer drug delivery systems
BP	Active ingredients and dosage forms with potential bioequivalence problems
BR	Suppositories or enemas that deliver drugs for systemic absorption
BS	Products having drug standard deficiencies
BT	Topical products with bioequivalence issues
BX	Drug products for which the data are insufficient to determine therapeutic equivalence

1. Orange Book Preface. Updated January 19, 2022. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#TEC. Accessed July 19, 2022.