

Bioequivalent

Identifying and definitional attributes

Metadata item type: Glossary Item

METEOR identifier: 606099

Registration status:

- [Commonwealth Department of Health](#), Standard 17/12/2015

Definition: In pharmacology, this term pertains to two formulations of the same drug that attain similar concentrations in blood and tissues at similar times with no clinically important differences between their therapeutic or adverse effects.

Two medicinal products containing the same active substance are considered bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities (rate and extent of absorption) after administration in the same molar dose lie within acceptable predefined limits.

The concept of bioequivalence is fundamental to the use of generic medicinal products.

Context: Pharmaceutical Benefits Scheme (PBS).

Source and reference attributes

Steward: Department of Health

Reference documents: Harris P, Nagy S, Vardaxis N (Editors) 2010. Mosby's Dictionary of Medicine, Nursing & Health Professions, 2nd Australian and New Zealand Edition. NSW: Mosby Elsevier, page 205.

European Medicines Agency 2010. Guideline on the Investigation of Bioequivalence, 20 January 2010. Viewed 9 April 2015, http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/01/WC500070039.pdf

Relational attributes

Metadata items which use this glossary item: [Bioequivalent allowed indicator](#)

- [Commonwealth Department of Health](#), Standard 17/12/2015

[Bioequivalent allowed indicator code A](#)

- [Commonwealth Department of Health](#), Standard 17/12/2015

[Pharmaceutical Benefits Scheme \(PBS\) prescription—bioequivalent allowed indicator](#)

- [Commonwealth Department of Health](#), Standard 17/12/2015

[Pharmaceutical Benefits Scheme \(PBS\) prescription—bioequivalent allowed indicator, code A](#)

- [Commonwealth Department of Health](#), Standard 17/12/2015