Bioequivalent

Exported from METEOR

(AIHW's Metadata Online Registry)

© Australian Institute of Health and Welfare 2024

This product, excluding the AIHW logo, Commonwealth Coat of Arms and any material owned by a third party or protected by a trademark, has been released under a Creative Commons BY 4.0 (CC BY 4.0) licence. Excluded material owned by third parties may include, for example, design and layout, images obtained under licence from third parties and signatures. We have made all reasonable efforts to identify and label material owned by third parties.

You may distribute, remix and build on this website’s material but must attribute the AIHW as the copyright holder, in line with our attribution policy. The full terms and conditions of this licence are available at https://creativecommons.org/licenses/by/4.0/.

Enquiries relating to copyright should be addressed to info@aihw.gov.au.

Enquiries or comments on the METEOR metadata or download should be directed to the METEOR team at meteor@aihw.gov.au.

# Bioequivalent

|  |
| --- |
| Identifying and definitional attributes |
| Metadata item type: | Glossary Item |
| METEOR identifier: | 606099 |
| Registration status: | [Commonwealth Department of Health](https://meteor.aihw.gov.au/RegistrationAuthority/10), Retired 19/10/2023 |
| 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 and Aged Care](https://meteor.aihw.gov.au/content/564862) |
| 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](https://meteor.aihw.gov.au/content/605595)[Commonwealth Department of Health](https://meteor.aihw.gov.au/RegistrationAuthority/10), Retired 19/10/2023[Bioequivalent allowed indicator code A](https://meteor.aihw.gov.au/content/612340)[Commonwealth Department of Health](https://meteor.aihw.gov.au/RegistrationAuthority/10), Retired 19/10/2023[Pharmaceutical Benefits Scheme (PBS) prescription—bioequivalent allowed indicator](https://meteor.aihw.gov.au/content/605948)[Commonwealth Department of Health](https://meteor.aihw.gov.au/RegistrationAuthority/10), Retired 19/10/2023[Pharmaceutical Benefits Scheme (PBS) prescription—bioequivalent allowed indicator, code A](https://meteor.aihw.gov.au/content/605962)[Commonwealth Department of Health](https://meteor.aihw.gov.au/RegistrationAuthority/10), Retired 19/10/2023 |