ACPS-LIBRARY:
Topics in Applied Clinical Pharmacology

Applied Clinical Pharmacokinetics - Guidelines

Bioanalytical method validation

EMA:

- EMEA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2** – Guideline on bioanalytical method validation (Jul.2011)
- EMA/INS/GCP/532137/2010 GCP Inspectors Working Group – Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (Feb.2012)
- Eudralex Volume 10 Chapter IV Annex VII to Guidance for the conduct of GCP inspections – Bioanalytical part, Pharmacokinetic and Statistical Analyses of Bioequivalence Trials (2008 – under EU Clinical Trial Directive 2001/20/EC)
- Eudralex Volume 10 Chapter IV Annex VII – to guidance for the conduct of good clinical practice inspections – bioanalytical part, pharmacokinetic and statistical analyses of bioequivalence trials (Nov.2017 – under EU Clinical trial Regulation 536/2014)

FDA:

- Guidance for Industry – Bioanalytical Method Validation (draft) – September 2013

ICH:

- Q2(R1): Validation Of Analytical Procedures: Text And Methodology
- M10: Bioanalytical Method Validation | Concept Paper

Japan:

- Guideline on Bioanalytical Method Validation in Pharmaceutical Development (2013) and Guideline on Bioanalytical Method (Ligand Binding Assay) Validation in Pharmaceutical Development

EURACHEM:

- The Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and Related Topics (2014)

See also

- Gaurav Tiwari and Ruchi Tiwari. Bioanalytical method validation: An updated review. Pharm Methods. 2010 Oct-Dec; 1(1): 25–38.

BABE-reporting templates

EMA:

- EMA/CHMP/600958/2010/Corr.*
  Appendix IV of the Guideline on the Investigation on Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1): Presentation of Biopharmaceutical and Bioanalytical Data in Module 2.7.1

FDA:

- Technical Specifications Document – Model Bioequivalence Data Summary Tables (Feb.2017)
- Good Review Practices: Clinical Pharmacology Review of New Molecular Entity (NME) New Drug Applications (NDAs) and Original Biologics License Applications (BLAs)

AUSTRALIA:

- Summary of a bioavailability or bioequivalence study

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BABE-Guidelines

EEA | EMA

- CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** : Guideline on the investigation of bioequivalence – 20 January 2010
- EMA/CHMP/600958/2010/Corr.:
  Appendix IV of the Guideline on the Investigation on Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1): Presentation of Biopharmaceutical and Bioanalytical Data in Module 2.7.1 (Nov.2011)
- EMA/618604/2008 Rev. 13 : Questions & Answers on the Bioavailability and Bioequivalence Guideline (Dec.2015)
- EMA/CHMP/423137/2013 : Concept paper on the development of product-specific guidance on demonstration of bioequivalence (Jul.2013)
- EMA/CHMP/EWP/280/96 : Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms (EMA/CPMP/EWP/280/96 Corr1) – Nov.2014
- EMA/CHMP/QWP/428693/2013 : Guideline on quality of oral modified release products – Mar.2014
- EMA/CHMP/QWP/608924/2014 : Guideline on quality of transdermal patches – Oct.2014
- CPMP/EWP/239/95 final: Note for guidance on the clinical requirements for locally applied, locally acting products containing known constituents – Nov.1995
- EMA/CHMP/QWP/558185/2014 : Concept paper on the development of a guideline on quality and equivalence of topical products – Dec.2014
- EMA/CHMP/558326/2013 : Concept paper on the development of a guideline on the demonstration of therapeutic equivalence for locally applied and locally acting products in the gastrointestinal tract – Sep.2013
- CPMP/EWP/239/95 Rev. 1 : Guideline on equivalence studies for the demonstration of therapeutic equivalence for products that are locally applied, locally acting in the gastrointestinal tract as addendum to the guideline on the clinical requirements for locally applied, locally acting products containing known constituents [Draft] – Mar.2017
- Eudralex Volume 10 Chapter IV Annex VII to Guidance for the conduct of GCP inspections – Bioanalytical part, Pharmacokinetic and Statistical Analyses of Bioequivalence Trials (2008 – under EU Clinical Trial Directive 2001/20/EC)
- Eudralex Volume 10 Chapter IV Annex VII – to guidance for the conduct of good clinical practice inspections – bioanalytical part, pharmacokinetic and statistical analyses of bioequivalence trials (Nov.2017 – under EU Clinical trial Regulation 536/2014)

US | FDA

- USA Code of Federal Regulations Title 21: Food and Drugs: Chapter I Food And Drug Administration, Department Of Health And Human Services | Part 320 – Bioavailability And Bioequivalence Requirements
- USA Code of Federal Regulations Title 21: Food and Drugs: Chapter I Food And Drug Administration, Department Of Health And Human Services | Part 314 – Applications for FDA approval to market a new drug
- USA Code of Federal Regulations Title 21: Food and Drugs: Chapter I Food And Drug Administration, Department Of Health And Human Services | Part 314 & 320 Requirements for Submission of Bioequivalence Data; Final Rule (2009)
- FDA Guidance for Industry – Statistical Approaches to Establishing Bioequivalence (Draft – Jan.2001)
- FDA Guidance for Industry – Food-Effect Bioavailability and Fed Bioequivalence Studies (Dec.2002)

- FDA Guidance for Industry – Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations (Mar.2003)
- FDA Guidance for Industry – Submission of Summary Bioequivalence Data for ANDAs (May. 2011)
- FDA Guidance for Industry – Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs – General Considerations (Mar.2014)

WHO

- WHO Technical Report Series No. 937 – WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fortieth Report (WHO Technical Report Series No. 937) – Full report | May 2006
- WHO Technical Report Series, No. 992, Annex 7 with a New Appendix 2. WHO Technical Report Series, No. 1003, 2017, Annex 6: Multisource (Generic) Pharmaceutical Products: Guidelines on Registration Requirements to Establish Interchangeability. Republication of Multisource (Generic) Pharmaceutical Products: Guidelines on Registration Requirements to Establish Interchangeability,
- WHO Technical Report Series No. 937 – Annex 8: Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms
- WHO Technical Report Series No. 937 – Annex 9: Additional guidance for organizations performing in vivo bioequivalence studies

ASEAN

- ASEAN Guidelines for the conduct of bioavailability and bioequivalence studies (2004)
- ASEAN Guidelines for the conduct of bioequivalence studies (R1 – 2015)

AUSTRALIA

- Guidance 15: Biopharmaceutic studies (Previously ARGPM 15: Biopharmaceutic)

CANADA

- Guidance Document: Conduct and Analysis of Comparative Bioavailability Studies [2012-06-06]
- Notice: Clarification of bioanalytical method validation procedures [2015-10-08]
- Notice: Policy on Bioequivalence Standards for Highly Variable Drug Products [2016-04-18]
- Guidance Document: Comparative Bioavailability Standards: Formulations use for Systemic Effects [2012-05-22]
- Draft Guidance for Industry: Preparation of Comparative Bioavailability Information for Drug Submissions in the CTD Format [2004-05-12]
- Guidance Document: Biopharmaceutics Classification System Based Biowaiver [2014-05-29]

EGYPT

- Egyptian Guideline For Conducting Bioequivalence Studies For Marketing Authorization Of Generic Products (Last update 02/03/2017)
- Regulatory Guidelines for bioequivalence centers (Last update 09/11/2017)
- Check List of Licensing Requirements For Bioequivalence Centers
- Format and Content of Bioequivalence Study Report
- Format and Content of Comparative in vitro dissolution Study Report
- Format and Content of Dissolution Profile Study Report
- Required Documents for submission of studies' reports and appeals

INDIA

- Guidelines for bioavailability and bioequivalence studies (2005)

JAPAN

- Attachment 1 of Division-Notification 0229 No. 10 of the Pharmaceutical and Food Safety Bureau: Guideline for Bioequivalence Studies of Generic Products (Feb.2012)
- Attachment 4 of Division-Notification 0229 No. 10 of the Pharmaceutical and Food Safety Bureau: Guideline for Bioequivalence Studies for Different Oral Solid Dosage Forms (Feb.2012)
- See also: Ryosuke Kuribayashi, Scott Appleton. Comparison of Generic Drug Reviews for Marketing Authorization between Japan and Canada. Drugs R D. 2017 Sep; 17(3): 371–379.

RUSSIA

- Standards for bioequivalence testing 2004 [RU]
- Standards for bioequivalence testing 2008 [RU]
- Standards for bioequivalence testing 2008 [EN]