Curriculum Vitae

Personal information

Alfredo García-Arieta

Work experience

1. Employer: Agencia Española de Medicamentos y Productos Sanitarios
   - Start date: 021997
   - End date: 112001
   - Position: Clinical Assessor
   - Activities: Assessment of the clinical documetation of full and abbreviated applications
   - Country: Spain
2. Employer: Agencia Española de Medicamentos y Productos Sanitarios
   - Start date: 112001
   - End date:
   - Position: Jefe de Sección/Servicio/Area de Farmacocinética y Medicamentos Genéricos
   - Activities: Assessment of the pharmacokinetic documentation of full and abbreviated applications Reviewer of the pharmacokinetic assessments Assessment of the bioequivalence demonstration in applications of locally acting products Protocol assessment Scientific advice
   - Country: Spain

Education and training

1. Subject: Universidad Complutense de Madrid
   - Start date: 101988
   - End date: 071993
   - Qualification: Pharmacy Degree
   - Organisation:
   - Country: Spain
2. Subject: Universidad Complutense de Madrid
   - Start date: 091993
   - End date: 071999
   - Qualification: PhD in Pharmaceutical Technology
   - Organisation:
   - Country: Spain
3. Subject: Universidad Complutense de Madrid
   - Start date: 101994
   - End date: 071996
   - Qualification: Master in Pharmaceutical Technology
   - Organisation:
   - Country: Spain
4. Subject: Universidad Autónoma de Barcelona
   - Start date: 091998
   - End date: 072004
   - Qualification: Master in Statistics in Health Sciences
   - Organisation:
   - Country: Spain
5. Subject: Ministerio de Educación y Ciencia
   - Start date:
   - End date: 2006
   - Qualification: Specialist in Pharmaceutical Technology
   - Organisation:
   - Country: Spain

Additional information

Publications

SCIENTIFIC PAPERS

García_Arieta A, Gordon J, Gwaza L, Merino V, Mangas_Sanjuan V. Regulatory Requirements for the Development of Second_Entry Semisolid Topical Products in the European Union. Pharmaceutics. 2023 Feb 10;15(2):601. doi: 10.3390/pharmaceutics15020601.

Mangas_Sanjuán V, Simón M, González_Rojano E, Ochoa D, Abad_Santos F, Román M, Ramos M, Govantes C, García_Arieta A. Alternative Pharmacokinetic Metrics in Single_Dose Studies to Ensure Bioequivalence of Prolonged_Release Products at Steady State_A Case Study. Pharmaceutics. 2023 Jan 26;15(2):409. doi: 10.3390/pharmaceutics15020409.

Manolis E, García_Arieta A, Lindahl A, Kotzagiorgis E, Limberg J, Holte Ø, Paixao P, Versantvoort C, Tshinanu FM, Blake K, Van Den Heuvel M. Using mechanistic models to support development of complex generic drug products: European Medicines Agency perspective. CPT Pharmacometrics Syst Pharmacol. 2023 Jan 11. doi: 10.1002/psp4.12906.

González_Álvarez I, Sánchez_Dengra B, Rodriguez_Galvez R, Ruiz_Picazo A, González_Álvarez M, García_Arieta A, Bermejo M. Exploring a Bioequivalence Failure for Silodosin Products Due to Disintegrant Excipients. Pharmaceutics. 2022 Nov 23;14(12):2565. doi: 10.3390/pharmaceutics14122565.

Paixão P, Silva N, Guerreiro RB, Blake K, Bonelli M, Morais JAG, García_ Arieta A, Gouveia LF. Evaluation of a Proposed Approach for the Determination of the Bioequivalence Acceptance Range for Narrow Therapeutic Index Drugs in the European Union. Pharmaceutics. 2022 Oct 31;14(11):2349. doi: 10.3390/pharmaceutics14112349.

Reig_López J, Merino_Sanjuan M, García_Arieta A, Mangas_Sanjuán V. A physiologically based pharmacokinetic model for open acid and lactone forms of atorvastatin and metabolites to assess the drug_gene interaction with SLCO1B1 polymorphisms. Biomed Pharmacother. 2022 Dec;156:113914. doi: 10.1016/j.biopha.2022.113914.

Tam A, Garcia_Arieta A, Abalos I, Agostinho Freitas Fernandes E, Mendes Lima Santos G, Rodriguez Martinez Z, Divinsky M, Kariv R, Potthast H, Braddy AC, Rodrigues C, Guzman Aurela E, Carolina Arevalo Gonzalez L, Gutierres Triana D, Jones B, Ahn C, Kim H, Kim SH, Kuribayashi R, Myoenzono A, Shimojo K, Van Oudtshoorn J, Bigler C, Meincke R, Roost MS, Walther C, Hsu LF, Crane C, Jarman T. A Survey of the Criteria Used for the Selection of Alternative Comparator Products by Participating Regulators and Organizations of the International Pharmaceutical Regulators Programme. J Pharm Pharm Sci. 2022;25:323_339. doi: 10.18433/jpps33081.

Cámara_Martinez I, Blechar JA, Ruiz_Picazo A, Garcia_Arieta A, Calandria C, Merino_Sanjuan V, Langguth P, Gonzalez_Alvarez M, Bermejo M, Al_Gousous J, Gonzalez_Alvarez I. Level A IVIVC for immediate release tablets confirms in vivo predictive dissolution testing for ibuprofen. Int J Pharm. 2022; 614:121415. doi: 10.1016/j.ijpharm.2021.121415.

Roost MS, Potthast H, Walther C, García_Arieta A, Abalos I, Agostinho Freitas Fernandes E, Mendes Lima Santos G, Rodríguez Martínez Z, Tam A, Rodrigues C, Gutierrez Triana DA, Guzmán Aurela E, Rodríguez Rodríguez N, Aeh Park S, Kim J, Kariv R, Divinsky M, Jones B, Kuribayashi R, Myoenzono A, Kasuga M, Van Oudtshoorn J, Chi JF, Hung WY, Hsu LF, Crane C, Jarman T, Braddy A. Requirements for Additional Strength Biowaivers for Modified Release Solid Oral Dosage Forms in International Pharmaceutical Regulators Programme Participating Regulators and Organisations: Differences and Commonalities. J Pharm Pharm Sci. 2021; 24:548_562. doi: 10.18433/jpps32260.

Paixão P, Guerreiro RB, Silva N, Blake K, Bonelli M, Morais JAG, Garcia Arieta A, Gouveia LF. A Proposed Approach for the Determination of the Bioequivalence Acceptance Range for Narrow Therapeutic Index Drugs in the European Union. Clin Pharmacol Ther. 2022; 111(2):470_476. doi: 10.1002/cpt.2451.

Xu Z, Merino_Sanjuan M, Mangas_Sanjuan V, García_Arieta A. Estimators and confidence intervals of f2 using bootstrap methodology for the comparison of dissolution profiles. Comput Methods Programs Biomed. 2021; 212:106449. doi: 10.1016/j.cmpb.2021.106449.

Reig_López J, García_Arieta A, Mangas_Sanjuán V, Merino_Sanjuán M. Current Evidence, Challenges, and Opportunities of Physiologically Based Pharmacokinetic Models of Atorvastatin for Decision Making. Pharmaceutics. 2021; 13(5):709. doi: 10.3390/pharmaceutics13050709.

Prieto_Escolar M, Torrado JJ, Álvarez C, Ruiz_Picazo A, Simón_Vázquez M, Govantes C, Frias J, García_Arieta A, Gonzalez_Alvarez I, Bermejo M. One and Two_Step In Vitro_In Vivo Correlations Based on USP IV Dynamic Dissolution Applied to Four Sodium Montelukast Products. Pharmaceutics. 2021; 13(5):690. doi: 10.3390/pharmaceutics13050690.

Ochoa D, Saiz_Rodríguez M, González_Rojano E, Román M, Sánchez_Rojas S, Wojnicz A, Ruiz_Nuño A, García_Arieta A, Abad_Santos F. High_Fat Breakfast Increases Bioavailability of Albendazole Compared to Low_Fat Breakfast: Single_Dose Study in Healthy Subjects. Front Pharmacol. 2021; 12:664465. doi: 10.3389/fphar.2021.664465.

Gonzalez_Alvarez I, Bermejo M, Tsume Y, Ruiz_Picazo A, Gonzalez_Alvarez M, Hens B, Garcia_Arieta A, Amidon GE, Amidon GL. An In Vivo Predictive Dissolution Methodology (iPD Methodology) with a BCS Class IIb Drug Can Predict the In Vivo Bioequivalence Results: Etoricoxib Products. Pharmaceutics. 2021; 13(4):507. doi: 10.3390/pharmaceutics13040507.

Garcia Arieta A, Simon C, Tam A, Mendes Lima Santos G, Freitas Fernandes EA, Rodríguez Martínez Z, Rodrigues C, Park SA, Kim J, Kim K, Kuribayashi R, Myoenzono A, Shimojo K, Walther C, Roost MS, Hung WY, Hsu LF, Crane C, Braddy AC, Van Oudtshoorn J, Gutierrez Triana DA, Guzmán Aurela E, Jones B, Potthast H, Abalos I. A Survey of the Regulatory Requirements for the Waiver of In Vivo Bioequivalence Studies of Generic Products in Certain Dosage Forms by Participating Regulators and Organisations of the International Pharmaceutical Regulators Programme. J Pharm Pharm Sci. 2021; 24:113_126. doi: 10.18433/jpps31491.

Xu Z, Mangas_Sanjuán V, Merino_Sanjuán M, Merino V, García_Arieta A. Influence of Inter_ and Intra_Batch Variability on the Sample Size Required for Demonstration of Equivalent Microstructure of Semisolid Dosage Forms. Pharmaceutics. 2020;12(12):1159. doi: 10.3390/pharmaceutics12121159.

Figueroa_Campos A, Sánchez_Dengra B, Merino V, Dahan A, González_Álvarez I, García_Arieta A, González_Álvarez M, Bermejo M. Candesartan Cilexetil In Vitro_In Vivo Correlation: Predictive Dissolution as a Development Tool. Pharmaceutics. 2020; 12(7):633. doi: 10.3390/pharmaceutics12070633.

González_Rojano E, Marcotegui J, Laredo L, Gwaza L, Gordon J, Portolés A, Vargas E, Morales_Alcelay S, García_Arieta A. Chiral bioanalytical methods in bioequivalence studies of intravenous vs. oral formulations of ibuprofen. Chirality. 2020; 32(9):1169_1177. doi: 10.1002/chir.23258.

Ruiz_Picazo A, Colón_Useche S, Perez_Amorós B, González_Álvarez M, Molina_Martínez I, González_Álvarez I, García_Arieta A, Bermejo M. Investigation to Explain Bioequivalence Failure in Pravastatin Immediate_Release Products. Pharmaceutics. 2019; 11(12):663. doi: 10.3390/pharmaceutics11120663.

Matji A, Vargas E, Carvajal L, Terleira AI, Portolés A, Garcia_Arieta A, Torrado JJ, Serrano DR. Effect of enantiomerism on the bioequivalence of a new ibuprofen 600_mg tablet formulation obtained by roller compaction. Chirality. 2020; 32(2):185_190. doi: 10.1002/chir.23148.

Mangas_Sanjuán V, Pleguezuelos_Villa M, Merino_Sanjuán M, Hernández MJ, Nácher A, García_Arieta A, Peris D, Hidalgo I, Soler L, Sallan M, Merino V. Assessment of the Inter_Batch Variability of Microstructure Parameters in Topical Semisolids and Impact on the Demonstration of Equivalence. Pharmaceutics. 2019;11(10):503. doi: 10.3390/pharmaceutics11100503. Erratum in: Pharmaceutics. 2020; 12(5):E436. doi: 10.3390/pharmaceutics12050436

González_Rojano E, Marcotegui J, Ochoa D, Román M, Álvarez C, Gordon J, Abad_Santos F, García_Arieta A. Investigation on the Existence of Sex_By_Formulation Interaction in Bioequivalence Trials. Clin Pharmacol Ther. 2019; 106(5):1099_1112. doi: 10.1002/cpt.1539.

Pejčić Z, Vučićević K, García_Arieta A, Miljković B. Adjusted indirect comparisons to assess bioequivalence between generic clopidogrel products in Serbia. Br J Clin Pharmacol. 2019; 85(9):2059_2065. doi: 10.1111/bcp.13997.

Lenić I, Blake K, Garcia_Arieta A, Potthast H, Welink J. Overview of the European Medicines Agency's Experience With Biowaivers in Centralized Applications. Clin Transl Sci. 2019; 12(5):490_496. doi: 10.1111/cts.12642.

Bermejo M, Kuminek G, Al_Gousous J, Ruiz_Picazo A, Tsume Y, Garcia_Arieta A, González_Alvarez I, Hens B, Amidon GE, Rodriguez_Hornedo N, Amidon GL, Mudie D. Exploring Bioequivalence of Dexketoprofen Trometamol Drug Products with the Gastrointestinal Simulator (GIS) and Precipitation Pathways Analyses. Pharmaceutics. 2019; 11(3):122. doi: 10.3390/pharmaceutics11030122.

González_Rojano E, Marcotegui J, Morales_Alcelay S, Álvarez C, Gordon J, Abad_Santos F, García_Arieta A. Sex_by_formulation interaction in bioequivalence trials with transdermal patches. Eur J Clin Pharmacol. 2019; 75(6):801_808. doi: 10.1007/s00228_019_02632_1.

Garcia Arieta A, Simon C, Lima Santos GM, Calderón Lojero IO, Rodríguez Martínez Z, Rodrigues C, Park SA, Kim JM, Kuribayashi R, Okada Y, Nolting A, Pfäffli C, Hung WY, Crane C, Braddy AC, Van Oudtshoorn J, Gutierrez Triana D, Clarke M. A Survey of the Regulatory Requirements for the Acceptance of Foreign Comparator Products by Participating Regulators and Organizations of the International Generic Drug Regulators Programme. J Pharm Pharm Sci. 2019; 22(1):28_36. doi: 10.18433/jpps30215.

Crane C, Santos GML, Fernandes EAF, Simon C, Tam A, Triana DG, Potthast H, Kuribayashi R, Okada Y, Myoenzono A, Calderon IO, Rodriguez Z, Jones B, Park SA, Eum SY, Rodrigues C, Van Oudsthoorn J, Nolting A, Walther C, Roost MS, Hung WY, Braddy AC, Garcia_Arieta A. The Requirements for Additional Strength Biowaivers for Immediate Release Solid Oral Dosage Forms in International Pharmaceutical Regulators Programme Participating Regulators and Organisations: Differences and Commonalities. J Pharm Pharm Sci. 2019; 22(1):486_500. doi: 10.18433/jpps30724.

Alonso TR, Gagol A, Scherer M, Matji A, Torrado_Santiago S, Serrano DR, Garcia_Arieta A, Torrado JJ. A multivariate investigation into the relationship between pharmaceutical characteristics and patient preferences of bioequivalent ibuprofen tablets. Patient Prefer Adherence. 2018; 12:1927_1935. doi: 10.2147/PPA.S174479.

Ruiz Picazo A, Martinez_Martinez MT, Colón_Useche S, Iriarte R, Sánchez_Dengra B, González_Álvarez M, García_Arieta A, González_Álvarez I, Bermejo M. In Vitro Dissolution as a Tool for Formulation Selection: Telmisartan Two_Step IVIVC. Mol Pharm. 2018; 15(6):2307_2315. doi: 10.1021/acs.molpharmaceut.8b00153.

González_García I, García_Arieta A, Merino_Sanjuan M, Mangas_Sanjuan V, Bermejo M. Defining level A IVIVC dissolution specifications based on individual in vitro dissolution profiles of a controlled release formulation. Eur J Pharm Sci. 2018; 119:200_207. doi: 10.1016/j.ejps.2018.04.025.

González_Rojano E, Abad_Santos F, Ochoa D, Román M, Marcotegui J, Álvarez C, Gordon J, García_Arieta A. Evaluation of sex_by_formulation interaction in bioequivalence studies of efavirenz tablets. Br J Clin Pharmacol. 2018; 84(8):1729_1737. doi: 10.1111/bcp.13601.

Mangas_Sanjuan V, Navarro_Fontestad C, García_Arieta A, Trocóniz IF, Bermejo M. Computer simulations for bioequivalence trials: Selection of analyte in BCS class II and IV drugs with first_pass metabolism, two metabolic pathways and intestinal efflux transporter. Eur J Pharm Sci. 2018; 117:193_203. doi: 10.1016/j.ejps.2018.02.014.

Van Oudtshoorn JE, García_Arieta A, Santos GML, Crane C, Rodrigues C, Simon C, Kim JM, Park SA, Okada Y, Kuribayashi R, Pfäffli C, Nolting A, Lojero IOC, Martínez ZR, Hung WY, Braddy AC, Leal NA, Triana DG, Clarke M, Bachmann P. A Survey of the Regulatory Requirements for BCS_Based Biowaivers for Solid Oral Dosage Forms by Participating Regulators and Organisations of the International Generic Drug Regulators Programme. J Pharm Pharm Sci. 2018;21(1):27_37. doi: 10.18433/J3X93K.

Cardot JM, Garcia_Arieta A, Paixao P, Tasevska I, Davit B. Implementing the additional strength biowaiver for generics: EMA recommended approaches and challenges for a US_FDA submission. Eur J Pharm Sci. 2018; 111:399_408. doi: 10.1016/j.ejps.2017.10.013.

González_García I, Mangas_Sanjuan V, Merino_Sanjuán M, Álvarez_Álvarez C, Díaz_Garzón Marco J, Rodríguez_Bonnín MA, Langguth T, Torrado_Durán JJ, Langguth P, García_Arieta A, Bermejo M. IVIVC approach based on carbamazepine bioequivalence studies combination. Pharmazie. 2017; 72(8):449_455. doi: 10.1691/ph.2017.7011.

Global Harmonization of Comparator Products for Bioequivalence Studies. Gwaza L, Gordon J, Leufkens H, Stahl M, García_Arieta A. AAPS J. 2017 May;19(3):603_606. doi: 10.1208/s12248_017_0068_6. doi: 10.1208/s12248_016_9971_5.

Mangas_Sanjuan V, Colon_Useche S, Gonzalez_Alvarez I, Bermejo M, Garcia_Arieta A. Assessment of the Regulatory Methods for the Comparison of Highly Variable Dissolution Profiles. AAPS J. 2016; 18(6):1550_1561.

Gwaza L, Gordon J, Welink J, Potthast H, Leufkens H, Stahl M, García_Arieta A. Interchangeability between first_line generic antiretroviral products prequalified by WHO using adjusted indirect comparisons. Antivir Ther. 2017; 22(2):135_144. doi: 10.3851/IMP3089.

Cardot JM, Garcia Arieta A, Paixao P, Tasevska I, Davit B. Implementing the Biopharmaceutics Classification System in Drug Development: Reconciling Similarities, Differences, and Shared Challenges in the EMA and US_FDA_Recommended Approaches. AAPS J. 2016; 18(4):1039_46. doi: 10.1208/s12248_016_9915_0.

García_Arieta A, Ferrero_Cafiero JM, Puntes M, Gich I, Morales_Alcelay S, Tarré M, Font X, Antonijoan RM. Impact of Chiral Bioanalytical Methods on the Bioequivalence of Ibuprofen Products Containing Ibuprofen Lysinate and Ibuprofen Base. Chirality. 2016; 28(5):429_33. doi: 10.1002/chir.22598.

Colón_Useche S, González_Álvarez I, Mangas_Sanjuan V, González_Álvarez M, Pastoriza P, Molina_Martínez I, Bermejo M, García_Arieta A. Investigating the Discriminatory Power of BCS_Biowaiver in Vitro Methodology to Detect Bioavailability Differences between Immediate Release Products Containing a Class I Drug. Mol Pharm. 2015; 12(9):3167_74. doi: 10.1021/acs.molpharmaceut.5b00076.

Garcia_Arieta A, Gordon J, Gwaza L, Mangas_Sanjuan V, Álvarez C, Torrado JJ. Agitation Rate and Time for Complete Dissolution in BCS Biowaivers Based on Investigation of a BCS Biowaiver for Dexketoprofen Tablets. Mol Pharm. 2015; 12(9):3194_201. doi: 0.1021/acs.molpharmaceut.5b00131.

Gwaza L, Gordon J, Potthast H, Welink J, Leufkens H, Stahl M, García_Arieta A. Influence of point estimates and study power of bioequivalence studies on establishing bioequivalence between generics by adjusted indirect comparisons. Eur J Clin Pharmacol. 2015; 71(9):1083_9. doi: 10.1007/s00228_015_1889_9.

García_Arieta A, Gordon J, Potthast H. On the Biopharmaceutics Classification System Biowaiver of Ibuprofen. J Pharm Sci. 2015; 104(8):2429_32. doi: 10.1002/jps.24519.

Lee SL, Saluja B, García_Arieta A, Santos GM, Li Y, Lu S, Hou S, Rebello J, Vaidya A, Gogtay J, Purandare S, Lyapustina S. Regulatory Considerations for Approval of Generic Inhalation Drug Products in the US, EU, Brazil, China, and India. AAPS J. 2015; 17(5):1285_304. doi: 10.1208/s12248_015_9787_8.

Cuesta_Gragera A, Navarro_Fontestad C, Mangas_Sanjuan V, González_Álvarez I, García_Arieta A, Trocóniz IF, Casabó VG, Bermejo M. Semi_physiologic model validation and bioequivalence trials simulation to select the best analyte for acetylsalicylic acid. Eur J Pharm Sci. 2015; 74:86_94. doi: 10.1016/j.ejps.2015.04.002.

Cuesta_Gragera A, Navarro_Fontestad C, Mangas_Sanjuan V, González_Álvarez I, García_Arieta A, Trocóniz IF, Casabó VG, Bermejo M. Validation of a semi_physiological model for caffeine in healthy subjects and cirrhotic patients. Eur J Pharm Sci. 2015;73:57_63. doi: 10.1016/j.ejps.2015.03.018.

Morales_Alcelay S, de la Torre de Alvarado JM, García_Arieta A. On the Incorrect Statistical Calculations of the Kinetica Software Package in Imbalanced Designs. AAPS J. 2015; 17(4):1033_4. doi: 10.1208/s12248_015_9749_1.

García_Arieta A. A European Perspective on Orally Inhaled Products: In Vitro Requirements for a Biowaiver. J Aerosol Med Pulm Drug Deliv. 2014; 27(6):419_29. doi: 10.1089/jamp.2014.1130. Review.

García_Arieta A. Interactions between active pharmaceutical ingredients and excipients affecting bioavailability: Impact on bioequivalence. Eur J Pharm Sci. 2014; 65:89_97. doi: 10.1016/j.ejps.2014.09.004. PMID: 25236823

Gwaza L, Gordon J, Welink J, Potthast H, Leufkens H, Stahl M, García_Arieta A. Adjusted Indirect Treatment Comparison of the Bioavailability of WHO_Prequalified First_Line Generic Antituberculosis Medicines. Clin Pharmacol Ther. 2014; 96(5):580_8. doi: 10.1038/clpt.2014.144.

Boix_Montañes A, Garcia_Arieta A. Composition specification of teicoplanin based on its estimated relative bioavailability. Drug Dev Ind Pharm. 2015; 41(2):218_23. doi: 10.3109/03639045.2013.858733.

Herranz M, Morales_Alcelay S, Corredera_Hernández MT, de la Torre_Alvarado JM, Blázquez_Pérez A, Suárez_Gea ML, Alvarez C, García_Arieta A. Bioequivalence between generic tacrolimus products marketed in Spain by adjusted indirect comparison. Eur J Clin Pharmacol. 2013; 69(5):1157_62. doi: 10.1007/s00228_012_1456_6. PMID: 23196824.

Gwaza L, Gordon J, Welink J, Potthast H, Hansson H, Stahl M, García_Arieta A. Statistical approaches to indirectly compare bioequivalence between generics: a comparison of methodologies employing artemether/lumefantrine 20/120 mg tablets as prequalified by WHO. Eur J Clin Pharmacol. 2012; 68(12):1611_8. doi: 10.1007/s00228_012_1396_1

García_Arieta A, Gordon J. Bioequivalence requirements in the European Union: critical discussion. AAPS J. 2012; 14(4):738_48. doi: 10.1208/s12248_012_9382_1. Review.

Tsume Y, Langguth P, Garcia_Arieta A, Amidon GL. In silico prediction of drug dissolution and absorption with variation in intestinal pH for BCS class II weak acid drugs: ibuprofen and ketoprofen. Biopharm Drug Dispos. 2012; 33(7):366_77. doi: 10.1002/bdd.1800.

Polli JE, Cook JA, Davit BM, Dickinson PA, Argenti D, Barbour N, García_Arieta A, Geoffroy JM, Hartauer K, Li S, Mitra A, Muller FX, Purohit V, Sanchez_Felix M, Skoug JW, Tang K. Summary workshop report: Facilitating oral product development and reducing regulatory burden through novel approaches to assess bioavailability/bioequivalence. AAPS J. 2012; 14(3):627_38. doi: 10.1208/s12248_012_9376_z.

Evans C, Cipolla D, Chesworth T, Agurell E, Ahrens R, Conner D, Dissanayake S, Dolovich M, Doub W, Fuglsang A, García Arieta A, Golden M, Hermann R, Hochhaus G, Holmes S, Lafferty P, Lyapustina S, Nair P, O'Connor D, Parkins D, Peterson I, Reisner C, Sandell D, Singh GJ, Weda M, Watson P. Equivalence considerations for orally inhaled products for local action_ISAM/IPAC_RS European Workshop report. J Aerosol Med Pulm Drug Deliv. 2012; 25(3):117_39. doi: 10.1089/jamp.2011.0968.

Álvarez C, Gómez E, Simón M, Govantes C, Guerra P, Frías J, García_Arieta A. Differences in lercanidipine systemic exposure when administered according to labelling: in fasting state and 15 minutes before food intake. Eur J Clin Pharmacol. 2012; 68(7):1043_7. doi: 10.1007/s00228_012_1215_8.

García_Arieta A, Morales_Alcelay S, Herranz M, de la Torre_Alvarado JM, Blázquez_Pérez A, Suárez_Gea ML, Alvarez C. Investigation on the need of multiple dose bioequivalence studies for prolonged_release generic products. Int J Pharm. 2012; 423(2):321_5. doi: 10.1016/j.ijpharm.2011.11.022.

García_Arieta A, Blázquez A. Regulatory considerations for generic or biosimilar low molecular weight heparins. Curr Drug Discov Technol. 2012; 9(2):137_42. Review. doi: 10.2174/1570163811209020137.

Alvarez C, Núñez I, Torrado JJ, Gordon J, Potthast H, García_Arieta A. Investigation on the possibility of biowaivers for ibuprofen. J Pharm Sci. 2011;100(6):2343_9. doi: 10.1002/jps.22472.

Navarro_Fontestad C, González_Álvarez I, Fernández_Teruel C, García_Arieta A, Bermejo M, Casabó VG. Computer Simulations for Bioequivalence Trials: Selection of Analyte in BCS Drugs with first_pass Metabolism and Two Metabolic Pathways. Eur J Pharm Sci. 2010;41(5):716_728. doi: 10.1016/j.ejps.2010.09.017.

Torrado JJ, Blanco M, Farré M, Roset P, García_Arieta A. Rationale and Conditions for the Requirement of Chiral Bioanalytical Methods in Bioequivalence. Eur J Clin Pharmacol 2010; 66(6):599_604. doi: 10.1007/s00228_010_0792_7

Tothfalusi L, Endrenyi L, García Arieta A. Evaluation of bioequivalence for Highly Variable Drugs with Scaled Average Bioequivalence. Clin Pharmacokinet. 2009; 48(11):725_743. doi: 10.2165/11318040_000000000_00000.

Fernández_Teruel C, Gonzalez_Alvarez I, Navarro_Fontestad C, García_Arieta A, Bermejo M, Casabó VG. Computer simulations of bioequivalence trials: selection of design and analyte in BCS drugs with first_pass hepatic metabolism: Part II. Non_linear kinetics. Eur J Pharm Sci. 2009;36(1):147_56. doi: 10.1016/j.ejps.2008.10.023.

Fernández_Teruel C, Nalda Molina R, González_Alvarez I, Navarro_Fontestad C, García_Arieta A, Casabó VG, Bermejo M. Computer simulations of bioequivalence trials: selection of design and analyte in BCS drugs with first_pass hepatic metabolism: linear kinetics (I). Eur J Pharm Sci. 2009;36(1):137_46. doi: 10.1016/j.ejps.2008.10.014.

García_Arieta A, Abad_Santos F, Rodríguez_Martínez MA, Varas_Polo Y, Novalbos J, Laparidis N, Gallego_Sandín S, Orfanidis K, Torrado J. An eutomer/distomer ratio near unity does not justify non_enantiospecific assay methods in bioequivalence studies. Chirality. 2005;17(8):470_5. doi: 10.1002/chir.20186.

García_Arieta A., Torrado_Santiago S, Goya L, Torrado JJ. "Spried_Dried Powders as Nasal Absorption Enhancers of Cyanocobalamin". Biol. Pharm. Bull. 2001; 24(12): 1411_1416. doi: 10.1248/bpb.24.1411.

Torrado G, García_Arieta A, de los Ríos F, Menéndez JC and Torrado S. "Quantitative determination of dimethicone in commercial tablets and capsules by Fourier Transform Infrared Spectroscopy and Antifoaming Activity Test". Journal Pharmaceutical and Biomedical Analysis. 1999; 19 (3_4): 285_292. doi: 10.1016/s0731_7085(98)00116_2.

García – Arieta A., Torrado _ Santiago D. and Torrado, J. J. "Comparative Study of Aqueous and Organic Enteric Coatings of Chlorpheniramine Maleate Tablets". Drug Development and Industrial Pharmacy. 1996; 22(7): 579_585.

García – Arieta, A., Torrado, S. and Torrado, J. J. "Influence of Drug Location on the Release of Coated Pellets". Pharmacie 50 (12): 830 (1995).

LETTERS TO THE EDITOR

González_Rojano E, Abad_Santos F, Gordon J, García_Arieta A. Response to 'Sex_by_formulation interaction in bioequivalence studies: the importance of formulations and experimental conditions' by Ibarra et al. Br J Clin Pharmacol. 2019 Apr;85(4):857_858. doi: 10.1111/bcp.13860.

García_Arieta A, Gordon J, Potthast H. On the Effect of Common Excipients on the Oral Absorption of Class 3 Drugs.J Pharm Sci. 2016; 105(4):1353_4. doi: 10.1016/j.xphs.2016.01.005.

García_Arieta A, Gordon J, Potthast H. On the Biopharmaceutics Classification System Biowaiver of Ibuprofen. J Pharm Sci. 2015; 104(8):2429_32. doi: 10.1002/jps.24519.

Boix_Montañes A, Garcia_Arieta A. About the equivalence between different batches of a glycopeptide drug.Pharm Dev Technol. 2016; 21(5):642_5. doi: 10.3109/10837450.2015.1035726.

Morales_Alcelay S, de la Torre de Alvarado JM, García_Arieta A. On the Incorrect Statistical Calculations of the Kinetica Software Package in Imbalanced Designs. AAPS J. 2015 Jul;17(4):1033_4. doi: 10.1208/s12248_015_9749_1.

García_Arieta A, Gordon J. On the BCS biowaivers of orally disintegrating tablets. Eur J Pharm Sci. 2014;66C:107_108. doi: 10.1016/j.ejps.2014.10.009.

Garcia Arieta A. Reasons to use stereoselective assay methods. Chirality. 2012; 24(7):499. doi: 10.1002/chir.22022.

García Arieta A. Assessing bioequivalence of generic antiepilepsy drugs by indirect comparisons. Ann Neurol. 2012; 71(5):724_5; author reply 725. doi: 10.1002/ana.23583.

Arieta AG. Establishing bioequivalence for orally inhaled drug products. Expert Opin Drug Deliv. 2011; 8(11):1533_4. doi: 10.1517/17425247.2011.617901.

García Arieta A. Efficacy and safety of Flutiform compared with individual fluticasone and formoterol reference products. Respir Med. 2011 Jun 22. doi: 10.1016/j.rmed.2011.06.002

García_Arieta A. Sensitive studies with a significant dose_response curve for inhaled corticosteroids to investigate equivalent relative potency are feasible. Br J Clin Pharmacol. 2011 Nov;72(5):832_3; author reply 834_5. doi: 10.1111/j.1365_2125.2011.04017.x.

Garcia_Arieta A, Blazquez_Perez A. [Interchangeability among therapeutics equivalents of lamotrigine]. Rev Neurol. 2011 Mar 1;52(5):319_20; author reply 320. Spanish.

García_Arieta A. How to compare two different metered_dose inhaler_valved holding chambers in the administration of salbutamol. Chest. 2010; 138(3):758_9; author reply 759_60. doi: 10.1378/chest.10_0815.

García_Arieta A. The failure to show bioequivalence is not evidence against generics. Br J Clin Pharmacol. 2010; 70(3):452_3. doi: 10.1111/j.1365_2125.2010.03684.x.

Arieta AG. Bioequivalence assessment of inhalation products: Interchangeability, study design and statistical methods. Pulm Pharmacol Ther. 2010 Jun;23(3):156_8. doi: 10.1016/j.pupt.2010.01.001

García_Arieta A. Clin Ther. 2009; 31(12):3021_2; Author Reply 3022_3. doi: 10.1016/j.clinthera.2009.12.020.

García Arieta A. On the superiority of BDP/FF HFA pMDI fixed combination over the free combination of BDP CFC pMDI and FF DPI. Respir Med. 2009; 103(12):1969_70; author reply 1971_2. doi: 10.1016/j.rmed.2009.03.025.

García Arieta A. On comparing different devices of inhalation products. Respir Med. 2009, 103(11): 1774_1775. doi: 10.1016/j.rmed.2009.02.017

Arieta AG. Frequent mistakes in equivalence studies of generic inhalation products. Respir Med. 2008;102(4):628_9. doi: 10.1016/j.rmed.2007.12.015

Arieta AG. The frequent deficiency of lack of assay sensitivity. Respir Med. 2007; 101(10):2230_1. doi: 10.1016/j.rmed.2007.05.013.

García Arieta A. Validity of in vitro tests on aqueous spray pumps as surrogates for nasal deposition, absorption, and biologic response. J Aerosol Med. 2007; 20(3):361_2. doi: 10.1089/jam.2007.0628.

García_Arieta A, Blázquez_Pérez A, de la Barrera PP, Pozo_Hernández C, Vargas_Castrillón E. A propósito de los antiepilépticos genéricos. Rev Neurol. 2006 Oct 1_15;43(7):446_8

Projects

Research in the area of Biopharmacy: _ In vitro dissolution tests able to predict in vivo bioequivalence _ Excipient effect on absorption / bioavailability _ Bioequivalence and drug switchability

Memberships

Member of the Body of Pharmacists of the National Health, Spain

Member of the Pharmacokinetic Working Party

Coordinator of the Bioequivalence Working Group of EAMI (Encuentros de Autoridades Competentes en Medicamentos de los Países Iberoamericanos) _ Regulatory Authorities of the Iberoamerican countries

Co_chair of the Bioequivalence Working Group for Generics of the International Pharmaceutical Regulators Programme (IPRP), representing WHO.

Member of Expert Working Group of ICH M10. Bioanalytical method validation.

Other Relevant Information

External Consultant for Bioequivalence in the Prequalification Team _ Medicines (PQT/MED) of the World Health Organization.

Co_inventor of the patent “Procedure for the preparation by spray_drying of nasal powders using insoluble and swelling excipients as enhancers of nasal absorption”. No. of publication WO 01/19344 A1. Date of publication 22.3.2001. No. application: PCT/ES00/00346.