



Curriculum Vitae

Personal information **Paulo Paixão**

Work experience

1. Employer: Pharmacy Faculty of Lisbon University
 - Start date: 12/2019
 - End date:
 - Position: Assistant Professor
 - Activities:
 - Country: Portugal
2. Employer: European Medicines Agency
 - Start date: 07/2018
 - End date: 07/2019
 - Position: National Expert on Secondment
 - Activities:
 - Country: Netherlands
3. Employer: Pharmacy Faculty of Lisbon University
 - Start date: 09/2012
 - End date: 11/2019
 - Position: Invited Assistant Professor
 - Activities:
 - Country: Portugal
4. Employer: INFARMED
 - Start date: 10/2013
 - End date:
 - Position: Member of the Medicines Evaluation Board
 - Activities:
 - Country: Portugal
5. Employer: Pharmacy Faculty of Universidade Lusófona de Humanidades e Tecnologias
 - Start date: 09/2001
 - End date: 07/2018
 - Position: Assistant Professor
 - Activities:
 - Country: Portugal
6. Employer: College of Pharmacy, University of Michigan
 - Start date: 06/2016
 - End date: 09/2016
 - Position: Invited Assistant Researcher
 - Activities:
 - Country: United States
7. Employer: INFARMED
 - Start date: 10/2003
 - End date: 09/2013
 - Position: PK assessor
 - Activities:
 - Country: Portugal
8. Employer: Health School of Escola Superior de Saúde Ribeiro Sanches
 - Start date: 09/2002
 - End date: 12/2010
 - Position: Assistant Professor
 - Activities:
 - Country: Portugal
9. Employer: Pharmacy Faculty of Lisbon University
 - Start date: 01/1999
 - End date: 09/2001
 - Position: Scholarship Researcher
 - Activities:
 - Country: Portugal
10. Employer: INETI _ Instituto Nacional de Engenharia, Tecnologia e Inovação
 - Start date: 09/1997
 - End date: 09/1999
 - Position: Scholarship Researcher
 - Activities:
 - Country: Portugal

Education and training

1. Subject: Lisbon University
 - Start date: 2006
 - End date: 2010
 - Qualification: PhD in Pharmacy _ Pharmacokinetics
 - Organisation:
 - Country:
2. Subject: Lisbon University
 - Start date: 1999

- End date: 2002
 - Qualification: Master in Pharmacokinetics and Biopharmaceutics
 - Organisation:
 - Country:
3. Subject: Lisbon University
- Start date: 1992
 - End date: 1997
 - Qualification: Bachelors in Biochemistry
 - Organisation:
 - Country:

Additional information

Publications

- 1 Paixão P, Petric Z, Morais JAG. Physiologically Based Biopharmaceutics Model of Apixaban for Biopharmaceutics Risk Assessment. *Pharmaceutics*. 2025 Mar 18;17(3):382.
- 2 Paixao P, Garcia Arieta A, Silva N, Petric Z, Bonelli M, Morais JAG, Blake K, Gouveia LF. A Two-Way Proposal for the Determination of Bioequivalence for Narrow Therapeutic Index Drugs in the European Union. *Pharmaceutics*. 2024 Apr 28;16(5):598.
- 3 Petric Z, Gonçalves J, Paixão P. Infliximab in Inflammatory Bowel Disease: Leveraging Physiologically Based Pharmacokinetic Modeling in the Clinical Context. *Biomedicines*. 2024 Sep 1;12(9):1974.
- 4 Petric Z, Paixão P, Filipe A, Morais JAG. Clinical Pharmacology of Vinpocetine: Properties Revisited and Introduction of a Population Pharmacokinetic Model for Its Metabolite, Apovincaminic Acid (AVA). *Pharmaceutics*. 2023, 15(10), 2502.
- 5 Henriques SC, Paixão P, Almeida L, Silva NE. Predictive Potential of Cmax Bioequivalence in Pilot Bioavailability/Bioequivalence Studies, through the Alternative f_2 Similarity Factor Method. *Pharmaceutics*. 2023, 15(10), 2498.
- 6 Mehta M, Schug B, Blume HH, Beuerle G, Jiang W, Koenig J, Paixao P, Tampal N, Tsang YC, Walstab J, Wedemeyer R, Welink J. The Global Bioequivalence Harmonisation Initiative (GBHI): Report of the fifth international EUFEPS/AAPS conference. *Eur J Pharm Sci*. 2023 Aug 15;190:106566. doi: 10.1016/j.ejps.2023.106566
- 7 Henriques SC, Albuquerque J, Paixão P, Almeida L, Silva NE. Alternative Analysis Approaches for the Assessment of Pilot Bioavailability/Bioequivalence Studies. *Pharmaceutics*. 2023 May 7;15(5):1430.
- 8 Eftymios Manolis, Alfredo García-Arieta, Anders Lindahl, Evangelos Kotzagiorgis, Jobst Limberg, Øyvind Holte, Paulo Paixao, Carolien Versantvoort, Flora Musuamba Tshinanu, Kevin Blake, Michiel Van Den Heuvel. Using mechanistic models to support development of complex generic drug products: European Medicines Agency perspective. *CPT Pharmacometrics Syst Pharmacol* 2023 Jan 11.
- 9 Paixão, P.; Silva, N.; Guerreiro, R.B.; Blake, K.; Bonelli, M.; Morais, J.A.G.; García-Arieta, A.; Gouveia, L.F. 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.
- 10 Petric, Z.; Gonçalves, J.; Paixao, P. Under the Umbrella of Clinical Pharmacology: Inflammatory Bowel Disease, Infliximab and Adalimumab, and a Bridge to an Era of Biosimilars. *Pharmaceutics* 2022 Aug 24;14(9):1766.
- 11 Rosa, G. M. De L. L. D. .; Silva, S. R. B.; Yamada, S. S.; Paixão, P. J. P. A.; Montanha, M. C.; Kimura, E. Amoxicillin dosing and pharmacokinetics in obesity for the treatment of bacterial respiratory infection secondary to COVID-19: a systematic review. *Research, Society and Development*, [S. l.], v. 11, n. 14, p. e130111436040, 2022.
- 12 Paulo Paixão, Rita Bento Guerreiro, Nuno Silva, Kevin Blake, Milton Bonelli, Jose Augusto Guimarães Morais, Alfredo Garcia Arieta, Luis Filipe Gouveia; "A Proposed Approach for the Determination of the Bioequivalence Acceptance Range for Narrow Therapeutic Index Drugs in the European Union". *Clin Pharmacol Ther*. 2022 Feb;111(2):470-476. doi: 10.1002/cpt.2451. Online ahead of print.
- 13 Ana Luiza P P D P Soares, Maiara C Montanha, Conrado D S Alcantara, Sandra R B Silva, Cristina M Kuroda, Sérgio S Yamada, Antônio E Nicacio, Liane Maldaner, Jesui V Visentainer, Caroline F Simões, João Carlos Locatelli, Wendell A Lopes, Josmar Mazucheli, Andrea Diniz, Paulo J P A Paixão, Elza Kimura; "Pharmacokinetics of amoxicillin in obese and nonobese subjects". *Br J Clin Pharmacol* . 2021 Jan 20. doi: 10.1111/bcp.14739. Online ahead of print
- 14 Augustijns P, Vertzoni M, Reppas C, Langguth P, Lennernäs H, Abrahamsson B, Hasler WL, Baker JR, Vanuytsel T, Tack J, Corsetti M, Bermejo M, Paixão P, Amidon GL, Hens B.; "Unraveling the behavior of oral drug products inside the human gastrointestinal tract using the aspiration technique: History, methodology and applications.". *Eur J Pharm Sci*. 2020 Dec 1;155:105517
- 15 Bermejo M, Hens B, Dickens J, Mudie D, Paixão P, Tsume Y, Shedden K, Amidon GL.; "A Mechanistic Physiologically-Based Biopharmaceutics Modeling (PBBM) Approach to Assess the In Vivo Performance of an Orally Administered Drug Product: From IVIVC to IVIVP.". *Pharmaceutics*. 2020 Jan 17;12(1):74.
- 16 Isca VMS, Andrade J, Fernandes AS, Paixão P, Uriel C, Gómez AM, Duarte N, Riço P; "In Vitro Antimicrobial Activity of Isopimarane-Type Diterpenoids". *Molecules*. 2020 Sep 16;25(18):4250.
- 17 Paixão P; Kawakami K; Bermejo M; Tsume Y; Nuno Silva; Moribe K; Morais JAG; Amidon GL; Yamashita S; "Report from the 3rd International Symposium on BA/BE of Oral Drug Products: Biopharmaceutics meets Galenics"; *Journal of Drug Delivery Science and Technology*, 2020, Volume 56, Part B, 101274
- 18 Montanha MC, Diniz A, Silva NMEN, Kimura E, Paixão P.; "Physiologically-Based Pharmacokinetic Model on the Oral Drug Absorption in Roux-en-Y Gastric Bypass Bariatric Patients: Amoxicillin Tablet and Suspension.". *Mol Pharm*. 2019 Dec 2;16(12):5025-5034
- 19 Montanha MC, Dos Santos Magon TF, de Souza Alcantara C, Simões CF, Silva SRB, Kuroda CM, Yamada SS, de Oliveira LES, Nasser D, Junior NN, Mazucheli J, Diniz A, Paixão PJPA, Kimura E.; "Reduced bioavailability of oral amoxicillin tablets compared to suspensions in Roux-en-Y gastric bypass bariatric subjects.". *Br J Clin Pharmacol*. 2019 Sep;85(9):2118-2125
- 20 Paixão P, Bermejo M, Hens B, Tsume Y, Dickens J, Shedden K, Salehi N, Koenigsknecht MJ, Baker JR, Hasler WL, Lionberger R, Fan J, Wysocki J, Wen B, Lee A, Frances A, Amidon GE, Yu A, Benninghoff G, Löbenberg R, Talattof A, Sun D, Amidon GL.; "Linking the Gastrointestinal Behavior of Ibuprofen with the Systemic Exposure between and within Humans-Part 2: Fed State". *Mol Pharm*. Nov 12, 2018
- 21 Bermejo M, Paixão P, Hens B, Tsume Y, Koenigsknecht MJ, Baker JR, Hasler WL, Lionberger R, Fan J, Dickens J, Shedden K, Wen B, Wysocki J, Löbenberg R, Lee A, Frances A, Amidon GE, Yu A, Salehi N, Talattof A, Benninghoff G, Sun D, Kuminek G, Cavanagh KL, Rodríguez-Hornedo N, Amidon GL.; "Linking the Gastrointestinal Behavior of Ibuprofen with the Systemic Exposure between and within Humans-Part 1: Fasted State Conditions". *Mol Pharm*. Nov 12, 2018
- 22 Bart Hens, Jozef Al-Gousous, Kai Wang, Niloufar Salehi, Robert M. Ziff, Yasuhiro Tsume, Marival Bermejo, Paulo Paixão, James G. Brasseur, Alex Yu, Arjang Talattof, Gail Benninghoff, Peter Langguth, Hans Lennernäs, William L. Hasler, Luca Marciani, Duxin Sun, Gregory E. Amidon, Joseph Dickens, Kerby Shedden, Raimar Löbenberg, and Gordon L. Amidon; "Summary of the In Vivo Predictive Dissolution (iPD) – Oral Drug Delivery (ODD) Conference 2018". *Dissolution Technologies*. 25(2), 50-53, 2018
- 23 Hens B, Sinko PD, Job N, Dean M, Al-Gousous J, Salehi N, Ziff RM, Tsume Y, Bermejo M, Paixão P, Brasseur JG, Yu A, Talattof A, Benninghoff G, Langguth P, Lennernäs H, Hasler WL, Marciani L, Dickens J, Shedden K, Sun D, Amidon GE, Amidon GL.; "Formulation predictive dissolution (fPD) testing to advance oral drug product development: An introduction to the US FDA funded '21st Century BA/BE' project". *Int J Pharm*. 548(1):120-127, 2018
- 24 Paixão P, Bermejo M, Hens B, Tsume Y, Dickens J, Shedden K, Salehi N, Koenigsknecht MJ, Baker JR, Hasler WL, Lionberger R, Fan J, Wysocki J, Wen B, Lee A, Frances A, Amidon GE, Yu A, Benninghoff G, Löbenberg R, Talattof A, Sun D, Amidon GL.; "Gastric emptying and intestinal appearance of nonabsorbable drugs phenol red and paromomycin in human subjects: A multi-compartment stomach approach". *Eur J Pharm Biopharm*. 129:162-174, 2018
- 25 Tukulula M, Gouveia L, Paixao P, Hayeshi R, Naicker B, Dube A; "Functionalization of PLGA Nanoparticles with

- 1,3-β-glucan Enhances the Intracellular Pharmacokinetics of Rifampicin in Macrophages". *Pharm Res.* 35(6):111, 2018
- 26 Hens B, Talattof A, Paixão P, Bermejo M, Tsume Y, Löbenberg R, Amidon GL; "Measuring the Impact of Gastrointestinal Variables on the Systemic Outcome of Two Suspensions of Posaconazole by a PBPK Model". *AAPS J.* 20(3):57, 2018
- 27 Cardot JM, Garcia-Arieta A, Paixao P, Tasevska I, Davit B; "Implementing the additional strength bio waiver for generics: EMA recommended approaches and challenges for a US-FDA submission". *Eur J Pharm Sci.* 111:399-408, 2017
- 28 Bart Hens, Yasuhiro Tsume, Marival Bermejo, Paulo Paixao, Mark J. Koenigsnecht, Jason R. Baker, William L. Hasler, Robert Lionberger, Jianghong Fan, Joseph Dickens, Kerby Shedden, Bo Wen, Jeffrey Wysocki, Raimar Loeberberg, Allen Lee, Ann Frances, Greg Amidon, Alex Yu, Gail Benninghoff, Niloufar Salehi, Arjang Talattof, Duxin Sun, Gordon L. Amidon; "Low Buffer Capacity and Alternating Motility along the Human Gastrointestinal Tract: Implications for in Vivo Dissolution and Absorption of Ionizable Drugs". *Mol. Pharmaceutics*, 14(12):4281-4294, 2017
- 29 Paixão P, Gouveia LF, Silva N, Morais JA.; Evaluation of dissolution profile similarity - Comparison between the f2, the multivariate statistical distance and the f2 bootstrapping methods. *Eur J Pharm Biopharm.* 112:67-74, 2017
- 30 Duarte H, Cruz JP, Aniceto N, Ribeiro AC, Fernandes A, Paixão P, Antunes F, Morais J.; "Population Approach to Efavirenz Therapy". *J Pharm Sci.* Epub ahead of print, 2017
- 31 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*, 18(4):1039-46, 2016
- 32 Paixão, Paulo (corresponding author); Aniceto, Natália; Gouveia, Luís F.; Morais, José A.G.; Prediction of Drug Distribution in Rat and Humans Using an Artificial Neural Networks Ensemble and a PBPK Model. *Pharmaceutical research*, May 2014
- 33 Paixão, Paulo (corresponding author); Aniceto, Natália; Gouveia, Luís F.; Morais, José A.G.; Tissue-to-blood distribution coefficients in the rat: Utility for estimation of the volume of distribution in man. *European Journal of Pharmaceutical Sciences*, v. 50, n. 3-4, p. 526-543, 2013
- 34 Paixão, Paulo (corresponding author); Gouveia, Luís F.; Morais, José A.G.; Prediction of the human oral bioavailability by using in vitro and in silico drug related parameters in a physiologically based absorption model. *International Journal of Pharmaceutics*, v.429, n. 1-2, p. 84-98, 2012
- 35 Paixão, Paulo (corresponding author); Gouveia, Luís F.; Morais, José A.G.; An alternative single dose parameter to avoid the need for steady-state studies on oral extended-release drug products. *European Journal of Pharmaceutics and Biopharmaceutics*, v. 80, n. 2, p. 410-417, 2012
- 36 Paixão, Paulo; Gouveia, Luís F.; Morais, José A.G.; Prediction of the in vitro permeability determined in Caco-2 cells by using artificial neural networks. *European Journal of Pharmaceutical Sciences*, v. 41, n. 1, p. 107-117, 2010
- 37 Paixão, Paulo; Gouveia, Luís F.; Morais, José A.G.; Prediction of the in vitro intrinsic clearance determined in suspensions of human hepatocytes by using artificial neural networks. *European Journal of Pharmaceutical Sciences*, v. 39, n. 5, p. 310-321, 2010
- 38 Paixão, Paulo; Gouveia, Luís F.; Morais, José A.G. Prediction of drug distribution within blood. *European Journal of Pharmaceutical Sciences*, v. 36, n. 4-5, p. 544-554, 2009
- 39 Paixão, Paulo; Use of artificial neural networks for outcome prediction in paraquat intoxications. *Revista Lusófona de Ciências e Tecnologias de Saúde*, v. 1, n. 2, p. 85-92, 2006.
- 40 Paixão, Paulo; Costa, P; Bugalho, T; Fidalgo, C; Pereira, L.; Simple method for determination of paraquat in plasma and serum of human patients by high-performance liquid chromatography. *Journal of Chromatography B*, v. 775, n. 1, p. 109-113, 2002
- 41 Constantino, L.; Paixão, Paulo; Moreira, R.; Portela, M.J.; Do Rosario, V.E.; Iley, J. Metabolism of primaquine by liver homogenate fractions. *Experimental and Toxicologic Pathology*, v. 51, n. 4-5, p. 299-303, 1999

Projects

As Coordinator; 1. "PopPK_PD of vancomycin on UCI patients" a joint project between FFUL and Hospital de S. Teotónio - Viseu. Period: 2012_15. As Researcher; 1. MCMember, COST Action CA21147, "ENOTTA _ European Network on Optimising Treatment with Therapeutic Antibodies in chronic inflammatory diseases". Period: 2022_2025

2. Researcher, "NPSTEENBRAIN - Novas Substâncias Psicoativas, Cérebro e Adolescência - Uma plataforma de Avaliação de Risco"; FCT aviso 02/SAICT/2017, projecto: 32515. Period: 2018_2020. (€223.673,00)

3. MCMember, COST Action CA16205, "UNGAP _ European Network on Understanding Gastrointestinal Absorption related processes". Period: 2017_2021

4. Invited Researcher, (FDA contract Number HHSF223201310144C) in the project "Innovations in Regulatory Science: in vivo Predictive Dissolution to Advance Oral Product Bioequivalence (BE) Regulation." (2016 _ 2019) (\$7.716.465,00)

5. Researcher, (European Commission reference HOME/2014/JDRU/AG/DRUG/7086) in the project "Identification and assessment of new psychoactive substances: a European network." (2016 _ 2019) (€601.087,06)

6. Researcher, (Instituto Português de Oncologia de Lisboa Francisco Gentil E.P.E. reference UIC/963) in the project "Monitorização terapêutica individualizada de Bussulfano em doentes submetidos a regimes de condicionamento pré_transplante de células progenitoras hematopoiéticas no IPO de Lisboa" (2014 _)

7. Researcher, (FCT reference PTDC/DTP_FTO/1747/2012) in the project "Pharmacokinetic/Pharmacogenetic modulation of HIV infection therapy by bayesian and artificial intelligence methods" (€140.000,00) (2012 _ 2015)

8. Pos_Doc Scholarship (FCT reference SFRH/BPD/69748/2010 (2011 _ 2012)) with the project "PBPK models for development of new drugs"

9. PhD scholarship (FCT reference SFRH/BD/28545/2006 (2006_2010)) with the project "PBPK models of absorption"

10. Research scholarship within UFEB (Unidade de farmacocinética e estudo biofarmacêuticos) financed by FCT (2000_2002) with the project "Toxicokinetics of Parauqat in Human Patients".

11. Research scholarship within the project "Development of cationic liposomes for DNA therapy", *Praxis XXI* nº 3/3.1/CTAE/1921/95, (1997 _ 2000)

12. Research Scholarship within the project "Metabolism of Primaquine in the rat" PCIB/BIA/2047/95 from FCT (1996_1997)

Memberships

Other Relevant Information