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Oral drug suspensions: Is *in vitro* dissolution testing relevant in predicting the *in vivo* performance?

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Dissolution testing conducted in physiological similar conditions is an useful tool in predicting issues related to pharmacokinetics, may indicate bioequivalence between certain products as solid oral dosage forms, and is employed to optimize the development and ensure the quality of drug formulations. According to Brazilian Health Surveillance Agency (Anvisa), European Medicines Agency (EMA) and Food and Drug Administration (FDA), comparative dissolution testing is required as a previous stage to the bioequivalence study between the new drug application (NDA) and abbreviated new drug application (ANDA), and also between NDA and similar (ANDA designated by a trademark) in Brazil. For oral suspensions, little information is available in the literature about the dissolution testing conditions, such as insertion and collection of the sample, influence of the system agitation, and others. In 1995, the first monograph including suspension dissolution testing was published in the United States Pharmacopeia (USP) 23. Dissolution testing was mentioned in one suspension monograph in Brazilian Pharmacopoeia 4th edition (2005) which was excluded in the 5th edition (2010). In USP 36 (2013), 12 suspension monographs include the test. Currently, 13 NDA, 17 ANDA and 9 similar oral suspensions are registered in Anvisa. Out of these, two (15.4%) NDA, three (17.6%) ANDA and one (11%) similar have monographs with dissolution test in USP 36. In this scenario, the establishment of the dissolution test conditions and its relevance in predicting *in vivo* performance of suspensions is paramount to subsidize their registration by the regulatory agencies.

Biography

Thaís dos Santos Paulino Soares did her Master's degree in Pharmaceutical Sciences from the Federal University of Ouro Preto. She graduated in Pharmacy, also from UFOP, in 2013. Currently, she is pursuing MBA in Regulatory Affairs at the Instituto de Pós Graduação (IPOG), in Belo Horizonte, Brazil.

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