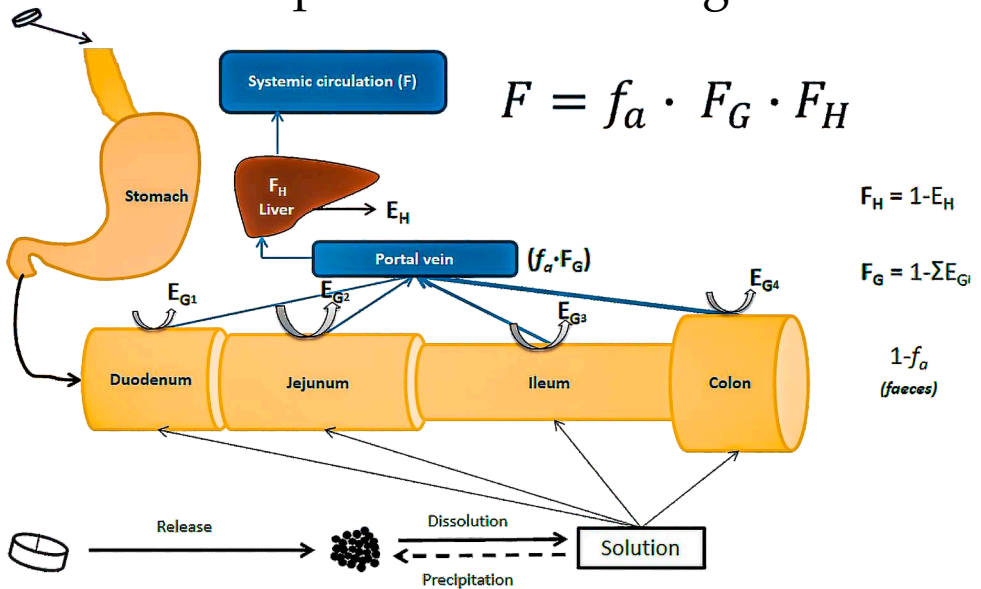


Webinar

DRUGS ARE ABSORBED IN FINITE TIME: Implications for Bioavailability/Bioequivalence/Biowaivers

14 December 2021, 15:00 (CET)

Oral absorption of solid dosage forms



NEW AVENUES ARE OPENED:

1. Estimation of absolute bioavailability from oral data exclusively
2. Towards a semi-biowaiver approach for failed biowaiver reports

ATHENA Research Centre organizes a half-day webinar on
Tuesday, 14 December 2021
covering the novel concept of finite time in oral drug absorption
and its implications on regulatory related issues (1-4).

Webinar summary

This half-day webinar is intended for Academics/students or scientists working in Academia, pharmaceutical industries, regulatory agencies, and contract research organizations.

The webinar will begin with a talk on the revision of oral drug absorption based on the concept of finite time of absorption. The absorption models rely on two principles: i) drugs are absorbed passively for a finite period of time, τ and ii) time absorption constrains linked with the gastrointestinal transit times of drug in the stomach, the small intestines and the colon are applied. Zero- or first-order input with a finite time duration is used for the development of the absorption models. Simulations based on various scenarios for model parameters and single or multiple input rates will be presented.

The second talk will provide an overview of the impact of the finite time drug absorption concepts on the scientific and regulatory aspects of bioavailability / bioequivalence / biowaivers. The meaning of the extent and rate of absorption parameters will be questioned, while the estimation of absolute bioavailability from oral data exclusively will be presented. This novel approach opens a new avenue towards the characterization of a drug as a “biowaiver”. The finite time of absorption concept can be also used for the expansion of biopharmaceutic classification system (BCS) to biopharmaceutic-pharmacokinetic classification system (BPCS) to facilitate drug discovery and development.

The third talk will focus on the analysis of concentration vs. time data using a **Physiologically Based Finite Time Pharmacokinetic (PBFTP)** software. Several case studies for data set analyses using the PBFTP software will be presented. Data will represent the time evolution of drug concentration in the blood stream after oral administration of formulations. A step-by-step approach for each case will guide researchers in choosing the most appropriate model and determining the optimum and realistic parameters. Physiological constraints will be considered in guiding the selection of model parameters.

The audience is invited to provide their data for an on-stage analysis.

1. P. Macheras. On an unphysical hypothesis of Bateman equation and its implications for pharmacokinetics. *Pharmaceutical Research*. 36:94 (2019)
2. P. Macheras, P. Chryssafidis. Revising Pharmacokinetics of Oral Drug Absorption: I Models Based on Biopharmaceutical/Physiological and Finite Absorption Time Concepts. *Pharmaceutical Research* 37, 187 (2020).
Erratum: *Pharm Res* 37, 206 (2020).
3. P. Chryssafidis, A. A. Tsekouras, P. Macheras. Revising Pharmacokinetics of Oral Drug Absorption: II Bioavailability-Bioequivalence Considerations. *Pharmaceutical Research* 38, 1345-1356 (2021)
4. A. A. Tsekouras, P. Macheras. Re-examining digoxin bioavailability after half a century: Time for changes in the bioavailability concepts. *Pharmaceutical Research*. In press.

TIME (CET)	SPEAKER	TOPIC
14:55	Ioannis Emiris , President, Research Center ATHENA , Athens, Greece	Welcome
15:00	Panos Macheras Department of Pharmacy, National and Kapodistrian University of Athens, and PharmaInformatics Unit, Research Center ATHENA, Athens, Greece	Drugs are absorbed in finite time.
15:55	Break	
16:00	Panos Macheras Department of Pharmacy, National and Kapodistrian University of Athens, and PharmaInformatics Unit, Research Center ATHENA, Athens, Greece	Drugs are absorbed in finite time: Implications for bioavailability / bioequivalence / biowaivers
17:00	Athanasios Tsekouras , Department of Chemistry, National and Kapodistrian University of Athens, and PharmaInformatics Unit, Research Center ATHENA, Athens, Greece	Analysis of C, t data using the "PBFTPk" software
17:45-18.30	Discussion	

Registration fees: Industry, CROs : 300 €
Academia-Government: 150 €
Student : 50 €

Please register [here](#)