In vitro dissolution testing and in silico modeling for orally administered drug products

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Organisation

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SCOPE OF THE METHOD

The Method relates to	Human health
The Method is situated in	Basic Research, Education and training, Regulatory use - Routine production, Translational - Applied Research
Type of method	In silico

DESCRIPTION

Method keywords

PBPK modeling

in vitro dissolution testing

intestinal absorption

oral absorption

Scientific area keywords

Biopharmaceutics

drug products

pharmacometrics

pharmacokinetics

pharmacodynamics

Method description

Performing biopredictive dissolution tests in *in vitro* models that are frequently used in pharmaceutical and academic institutions and using these *in vitro* dissolution data as input for PBPK models to predict the systemic exposure of the drug in humans/patients.

Lab equipment

Dissolution beakers ;

Stirrers ;

Sampling material ;

Biorelevant media ;

PBPK software packages.

Method status

Published in peer reviewed journal

PROS, CONS & FUTURE POTENTIAL

Advantages

3R principle for sure! Also, these tests are much faster and less expensive compared to clinical trials as traditionally done during the drug development process.

Challenges

Not all physiological variables are integrated in *in vitro* dissolution methods which may result in sometimes false predictions in the end!

Modifications

Doing more clinical studies in the hospital with the focus on exploring human GI physiology so we have more information to optimize *in silico* and *in vitro* models.

Future & Other applications

Especially in regulatory science, this approach may lead to easier and faster drug product approvals. In the current setting, the time from drug discovery until marketing access takes about 12 years on average. This could significantly reduced if regulatory authorities revise their guidelines.

REFERENCES, ASSOCIATED DOCUMENTS AND OTHER INFORMATION

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Associated documents

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