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

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SCOPE OF THE METHOD

<table>
<thead>
<tr>
<th>The Method relates to</th>
<th>Human health</th>
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<tbody>
<tr>
<td>The Method is situated in</td>
<td>Basic Research, Education and training, Regulatory use - Routine production, Translational - Applied Research</td>
</tr>
<tr>
<td>Type of method</td>
<td>In silico</td>
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</tbody>
</table>

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**

**References**


Hens B., Kataoka M., Ueda K., Gao P., Tsume Y., Augustijns P., Kawakami K., Yamashita S. Biopredictive in vitro testing methods to assess intestinal drug absorption from supersaturating dosage forms. JDSST. 2019


Associated documents

Hens et al. posaconazole-final.pdf
FinalArticleASA.pdf