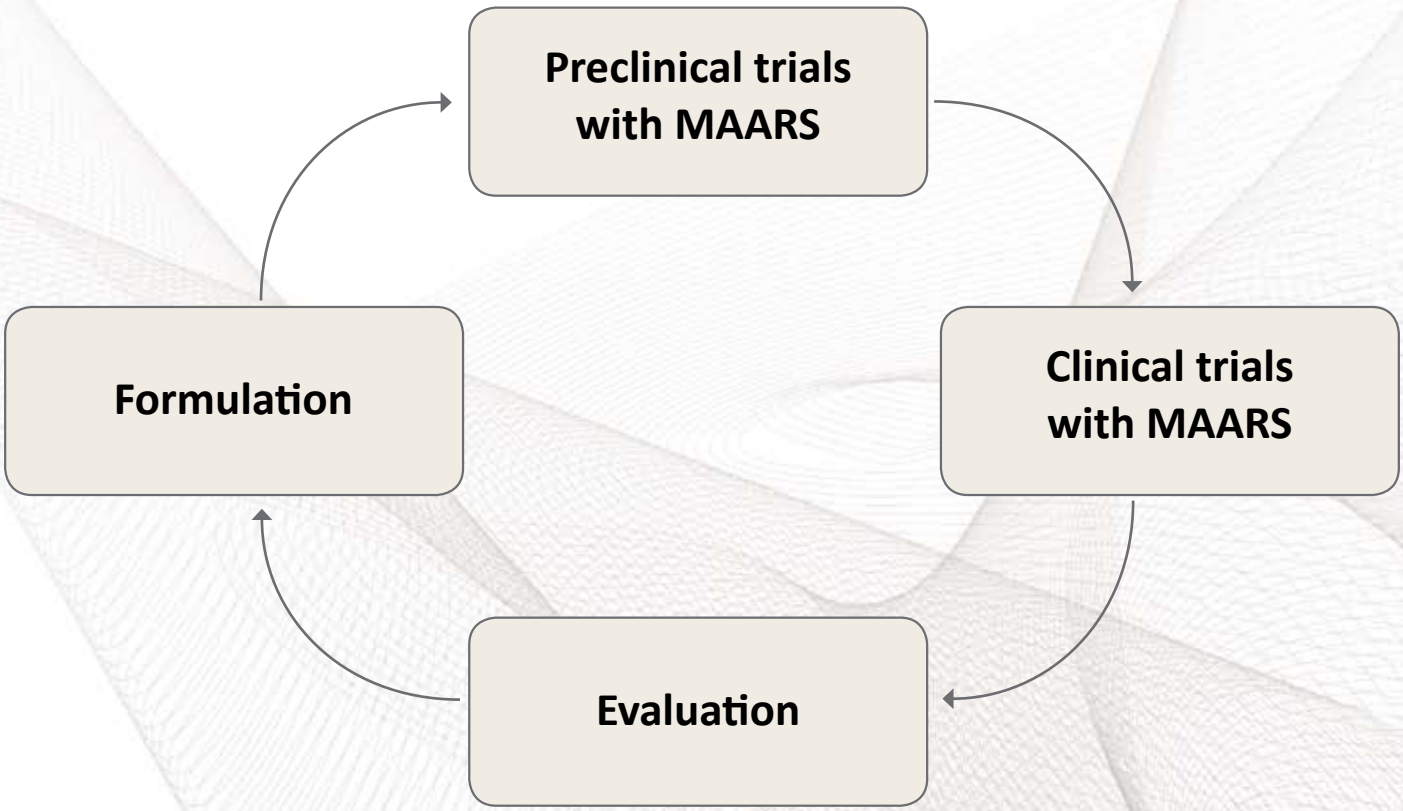
MAARS®

Magnetic Active Agent Release System

Oral drug development



www.pharmagnetic.de

MAARS – Overview

The majority of new active agents demand concentrated activities for the development of per oral dosage forms. The financial and temporal effort can be extremely high.
Evidence for the best appropriate excipients combination and the best absorption location already in the early development phase are essential for fast and cost efficient development.
MAARS helps to generate this information even before a first formulation is developed.

Approach

Magnetic localization of active agents by 3D-MAGMA:

- No ionizing radiation
- Exact 3d-real-time monitoring
- Accurate relation of 3d-position and position within the organ
- No shielding of disturbing magnetic fields
- 3D-MAGMA is a CE-certified medical device

Transport and release of active agents:

- Completely passive capsule inside the organism
- Large payloads
- Release triggered by short magnetic impulse
- Small capsule elements after release for an easy withdrawal
- Existing positive approval of local ethics commission for active magnetic drug release

Benefits

- Release of arbitrary drug formulations within the complete gastrointestinal tract
- Preclinical and clinical applications due to scalable capsules
- Solid and liquid dosage forms possible
- No radioactive marker necessary
- Low stress for the volunteers
- Fast results with moderate effort

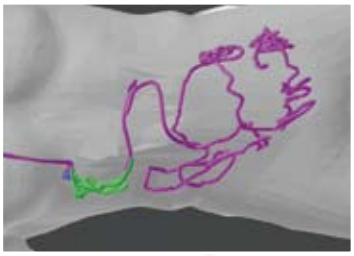
Offer

- Execution of preclinical and clinical absorption trials
- Customer oriented supervision of the complete development by qualified partners within the consortium

MAARS – Technology

Tracking of active agent containing capsule

- Magnetic marker monitoring with 3d-sensor array
- High spatial localization accuracy (± 3mm)
- High temporal resolution (100 Hz)
- Small magnetic capsule field
- No shielding of disturbing external magnetic fields
- Parallel monitoring of vital functions (ECG,…)



Active agent containing capsule

- Safe enclosing of active agents by magnetic forces
- Magnetic field signal for tracking of the capsule
- Small segments for safe withdrawal after release procedure
- High payload of up to 2.5 ml (at ⌀ = 12 mm, l = 25 mm)
- Scalable size of capsule ($⌀_{min}$ = 3 mm)
- FDA certified bioinert polymer shell

Release procedure

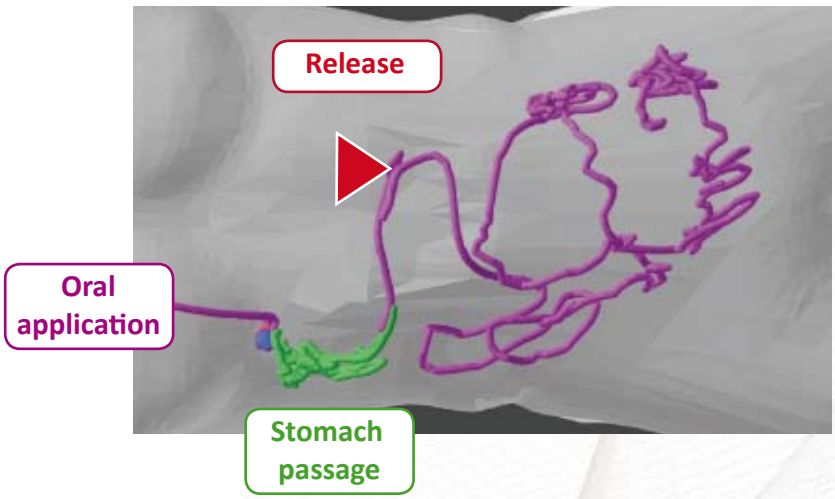
- Magnetic impulse (decaying alternating magnetic field)
- Magnetic field signal of capsule disappears → successful release
- Capsule destructs into small segments
- immediate and complete release of active agent

MAARS – Study

If an active agent is ready for animal and first in man studies
MAARS is the method which should be the next step.

Without specific galenic preparation every agent can be delivered
at any location within the gastrointestinal tract.

- Individual studies with small numbers of volunteers
- Preclinical studies on rat, rabbit and mini pig
- Early „first in man“ studies
- Execution of studies in specialized laboratories
- Easy handling of IMP
- Best suited for POC studies
- Short execution cycles
- Fast availability of results



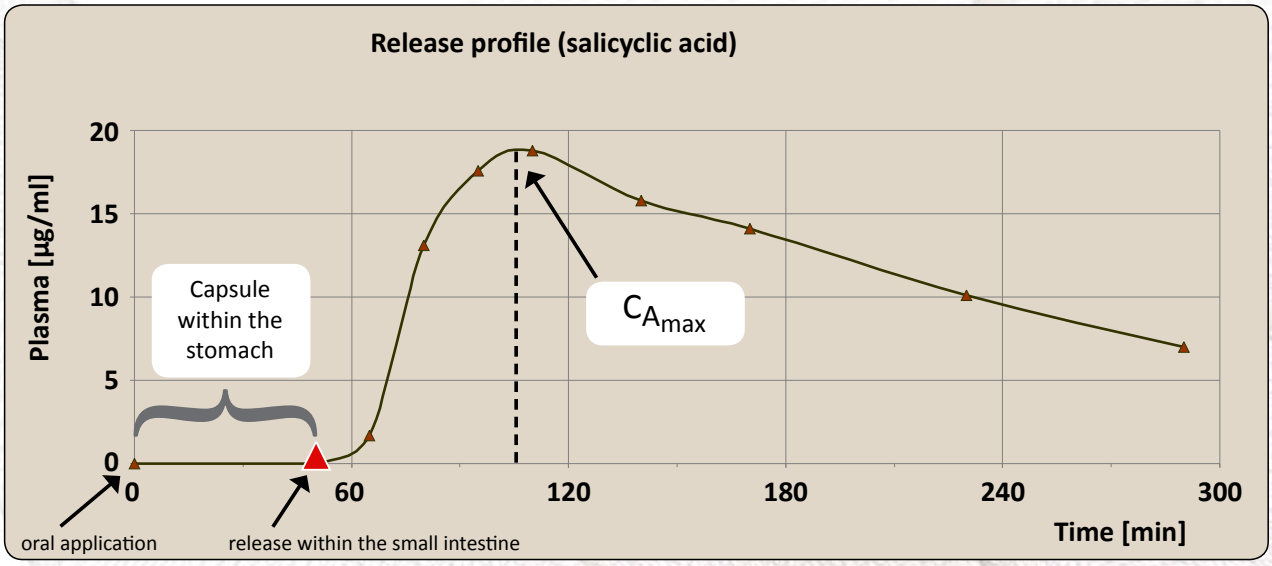


Fig.: A typically with MAARS measured release profile. 50 min after intake (capsule has left the stomach) the release was initiated (agent = Acetylsalicylic acid (ASA) powder). The resorption process always starts immediately. The maximum of salicylic acid concentration (metabolite of ASA) occurs another 50 min later.

MAARS – FAQ

How big is a MAARS capsule?

- The MAARS capsule is available equivalent to a normal medical capsule in sizes 000, 00, 0, 1, 2, 3 and 4.
- The maximum transport volume is approx. 2,5 ml

Is a MAARS trial reliable and safe for the volunteers?

- The release is initiated by a magnetic field impulse which is generated by a electromagnetic coil. This coil is positioned in front of the volunteer. At the surface of the coil exists for a short moment (~ 10 ms) a magnetic field of about 0.8 T which is 200-fold the earth magnetic field but only half the amount of a standard MRI-system.

- The temporal change of the magnetic field induces electrical current in electrical current conducting materials. That is the reason why there is induced a small electrical current inside the human body. This current is rather low but for very sensitive volunteers it can already stimulate neural activities which express themselves as slight prickle.

- At the moment of release the capsule moves slightly due to the occurring magnetic interaction. Because of the very short time of the limited magnetic impulse this movement is also very weak. The volunteer notices the release as a weak feeling of pressure and can give the information of the rough capsule position.

- The capsule elements consist of small metallic segments. These segments are coated completely by a bioinert polymere (Parylene). A chemical dissolution of elements (mostly iron, Chrome and Cobalt) is safely excluded.

Which exclusions are known?

- Volunteers with implants, especially with pacemakers
- Distinct obesity