Gamma Scintigraphy

for assessing formulation performance in man

What is **gamma scintigraphy**?

Gamma scintigraphy is a nuclear imaging technique that allows non-invasive *in vivo* assessment of dosage form behaviour. It has applications in oral, nasal, pulmonary and ophthalmic drug delivery, enabling visualisation of dosage form behaviour in the body.

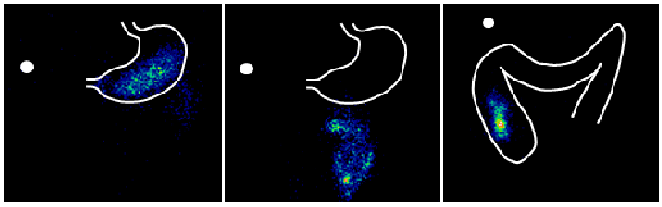
Gamma camera images courtesy of Siemens Healthcare

What **information** does it provide?

Gamma scintigraphy provides information on:

- Site of delivery
- Proof of concept *in vivo* and IVIVC
- Food effects
- Gastrointestinal transit and gastric emptying
- Intra- and inter-subject variability
- Pre-corneal residence
- Nasal residence

*The crucial early stage data afforded by gamma scintigraphy allows **informed** decision making, **streamlining** your development programme, **cutting costs** and **reducing time to market**.*



These scintigraphic images show disintegration of an oral dosage form in the (L-R) stomach, small intestine and colon.

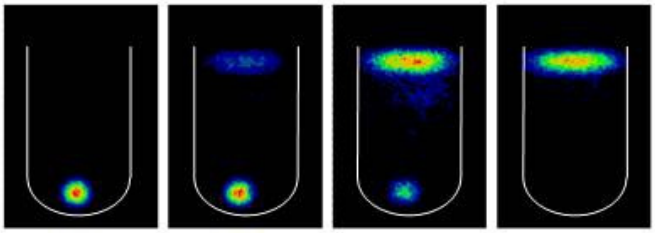
Why is this **useful**?

Having early access to information on the *in vivo* performance of your formulation greatly helps in deciding the next course of action in your formulation development or marketing strategy. Scintigraphy data can also be correlated with PK data in order to relate dosage form performance characteristics with plasma concentration.

Formulation **Radiolabelling**

Dosage forms are labelled with a radiopharmaceutical, frequently ^{99m}Tc or ^{111}In, and the radioactivity emitted is captured by the gamma camera to provide quantifiable images of formulation dispersion over time. Dual isotope labelling allows parallel assessment of two components of a formulation (such as a bilayer tablet) or meal gastric emptying and formulation behaviour.

Prior to the clinical phase, we will carry out *in vitro* testing to determine the optimal radiolabelling method for your dosage form. This may involve USP dissolution testing to validate the information that gamma scintigraphy is providing about your formulation.



These scintigraphic images show disintegration of a wax matrix tablet in a USPII dissolution vessel.

Clinical Expertise

We are a GCP and GMP compliant clinical research site with first class facilities. We will expertly transfer your technology to the clinical phase to produce data of the highest quality. Bio-Images' experienced clinical team undertake all aspects of the clinical trial process, including volunteer recruitment, ethics and regulatory approvals and complete trial management.

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