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Review Article

A BRIEF REVIEW ON GAMMA SCINTIGRAPHY FOR ANALYSIS OF CONTROLLED RELEASE DOSAGE FORMS

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ABSTRACT

Context: The drug release assessment increasingly accepted by imaging technologies .They give proof for their in vivo release of controlled and sustained release dosage forms. The imaging technologies are X-rays, magnetic resonance imaging and ultra sound, gamma scintigraphy. These are the tools for the assessment of oral, pulmonary, and ophthalmic dosage forms.

Objective: In this review mainly focus on gamma scintigraphy. This as a tool for the assessment of formulation deposition. Gamma scintigraphy is a non-invasive method with development of drug products and the assessment of pharmacodynamics effects in humans. From this method we can able to understand drug performance and critical parameters like gastrointestinal transit; gall bladder emptying; lung mucociliary clearance provides insights into the mode of action of drug candidates.

Methods: In this review focus on the functional terms of gamma scintigraphy and their applications in pharmacy. Deposition control, temporal control, Barrier control.

Keywords: Gamma scintigraphy, role in pharmacy, Oral drug delivery, functional terms.

INTRODUCTION

Gamma scintigraphy is a noninvasive method for the measurement of organ function, perfusion, receptor binding and also gives little anatomical information. This method involves the administration of a suitable labelled formulation containing a small amount of a gamma emitting substance [4].we can also name as nuclear medicine in pharmacy. Gamma scintigraphy is one such tool. It provides the means to assess critical-to-performance parameters, which in vitro methods attempt but often fail to predict. It also provides a gold standard method for the direct quantification of pharmacodynamics effects, providing insight into mode of action of drug candidates. The factor which effect the altered gastrointestinal transit due to individual variation, physiologic or pharmacologic factors, or the presence of food, may influence bio-availability. The Disintegration, or drug release from the product or delayed *in vivo*. Similarly, altered distribution, excretion or clearance from other routes of administration such as nasal, ocular, or inhalation may explain drug absorption anomalies.

Visualization is achieved by the incorporation of short half-life gamma emitting radionuclides, eg technetium-99m (99mTc) and indium-111 (111In). The chosen radionuclide(s) is used to label the drug product or, for pharmacodynamics investigations, the component of interest (eg food or fluid for gastrointestinal transit; inhaled particles for mucociliary clearance). The radiation dose to the subject is low– often not exceeding that received from a single X-ray.

- Technetium 99m: half-life 6hrs, mostly used radionuclide, used in oral, parenteral, pulmonary.
- Indium 111: half-life 2.8 days. Used as second component in the formulation
- Iodine123: half-life 13hrs
- Samarium 153: half- life 47hrs
- Carbon11: half -life 20. Used for functional imaging studies.

FUNCTIONAL TERMS

Controlled release technology branched into 3 main directions [5]

a. Deposition control: Deposition control refers to coverage of tissue achieved by the device.
b. Temporal control: It refers to devices that release of the active component. Ex: after administration by the oral route allowing exposure further down the gut
c. Barrier control: It refers to construction of devices in which excipients or film modulate the release of the drug

Gamma-scintigraphy is applied in design and development and evaluation of pharmaceutical drug delivery systems. It is used particularly for monitoring formulations in the gastrointestinal and respiratory tracts [6].Gastro intestinal track is important for absorption of most therapeutically agents. If system controls the release of a drug, a better dosing pattern and greater convenience to the patient can be improved by using conventional methods dissolution and kinetics rate also improved.gamma scintigraphy provides the information of deposition, dispersion and movement of the formulation of the drug. Scintigraphy evaluation of pharmaceutical dosage forms are being used increasingly at all stages of product development, and the assessment of prototype delivery systems [7]. Standard radiolabeling methods incorporate the radioactive marker in a finished product shortly before dose administration. Alternatively, neutron activation is a technique where a small amount of stable isotope is incorporated in the dosage form at the time of manufacture. This condition allows the product to be produced in the sponsor's facility under normal manufacturing conditions. The stable isotope is then converted to a radioactive isotope appropriate for gamma scintigraphy by a short exposure to a neutron flux [8].

GAMMA SCINTIGRAPY LABELLING FORMULATIONS

The drug entity cannot be labelled directly. The following strategies are employed [9].

1. Formulation matrix is radiolabeled with a tracer, it is associate with matrix only and is not released. This gives position data, no anatomical data. If the formulation is given by orally with 99mTC-DTPA- tagged drink imaging scheduled gives position and along with anatomical reference.
2. A radioisotope is admixed with drug and excipient during manufacture .the release of the tracer must be identified because it is similar to that drug difficult to identify the tracer in vitro studies. This will give information about release rates,

spreading, and position i.e. confirming that the coated tablet is performing functionally. While interpreting the data care should be taken only the drug will absorb not the tracer.

Solute Phase Markers

Sodium pertechnetate is available in nuclear medicine. This tracer is used targeting to brain, heart, skeleton, hepatobiliary system and lungs. For complex formulations like emulsions this type of tracer are used in the formulation [10].

Colloids And Fine Suspensions

Technetium -99m used in colloidal preparation used in lymphoscintigraphy.In the design of nanocolloids for lymph node imaging amphiphilic copolymers ,which spontaneously form colloidal particles range from 20-100nm[11].

Particulate Markers

Amberlite resigns bind technetium 99m and indium 111 are used to radioactive formulations for scintigraphy studies. In pharmacy Pellet formulations packed into hard gelatin capsules have Amerlite resin which gives controlled release formulations. In oral dosing intake of food gastric emptying time, density of the meal, volume of the meal effect the release of the drug [12].

RESULTS AND DISSCUSION

Gamma Scintigraphy Analysis in Controlled Drug Delivery

- Gamma scintigraphy, using a radioactive gas such as krypton 81 to outline the lung margins and measure the proportion of dose delivered to bronchi and alveolar of the lung.
- Double labelling is useful to monitor the transit time of different formulation administered in same time.i.e indium 111 and technetium 99.
- It is used to study the potential hazards of many drugs. Ex: bisphosphates analogues used in the treatment of osteoporosis.
- Gamma scintigraphy gives a complex absorption profile for isosorbide 5-mononitrate.
- Sustained release products can be labelled with In-111-labeeled with DTPA.
- Hydro gel plug used for colonic drug delivery for release of the drug.
- Products for oral inhalation can be radiolabeled by the addition of a radionuclide (eg 99mTc) to the formulation.

Nasal products

Nasal administration is used for delivery to the systemic circulation (large surface area, non-invasive delivery) or for local delivery (13). Delivery from nasal cavity has been explored to deliver drug to the sinuses, and also to the olfactory region to achieve delivery to the brain.

CONCLUSION

Gamma scintigraphy is a powerful tool for analyzing the drug in the human body. Few older methods gives assessing the behavior of drug formulation within the body but the methods does not provide any proof for the release of the drug. From gamma scintigraphy data we can able to understand the drug release rates, distribution of drug ,anatomical structure, measurement of transit time ,plasma – concentration time profile curves can be identified. From this information drug and true behavior and relationship within the body can assessed.

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