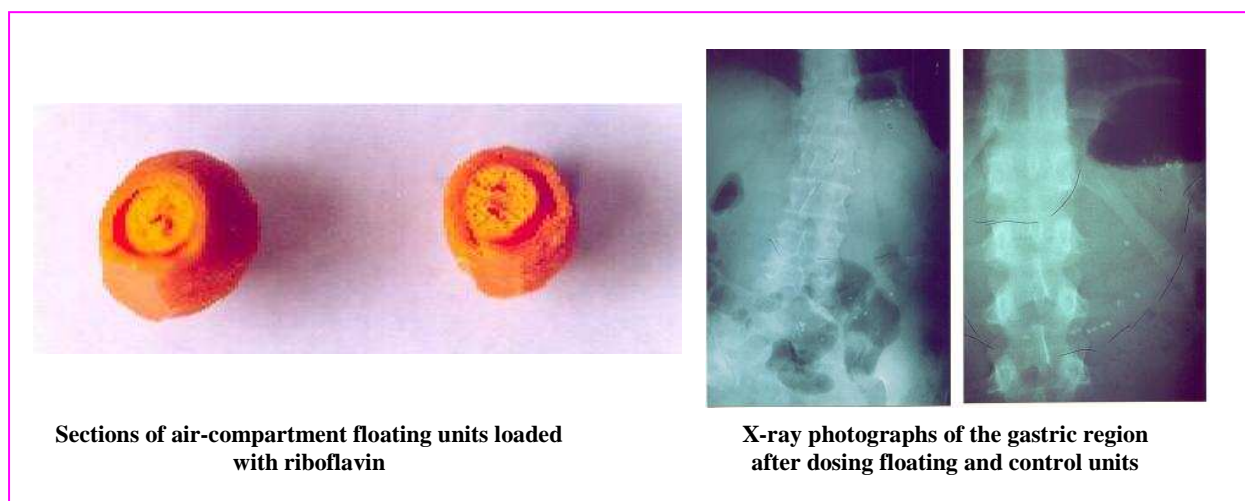


Multiple-unit device with prolonged intragastric residence

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A floating multiple-unit system, able to float immediately in the stomach, was designed. The floating units, analysed both *in vitro* and *in vivo*, showed actual buoyancy properties in human trials, prolonged and reproducible Gastric Residence Time (GRT) and increased bioavailability of a drug with an absorption window. More recently, the device has been evaluated as a carrier for antibiotics in the treatment of *Helicobacter pylori* infection.



Sections of air-compartment floating units loaded with riboflavin

X-ray photographs of the gastric region after dosing floating and control units

1. Description of the product

The multiple-unit device, constituted by calcium alginate beads with a size of about 4 mm and obtained by dropping sodium alginate water solution into a crosslinking medium containing calcium ions, is based on two different principles: a) presence of a floating compartment separating a calcium alginate core from a calcium alginate/PVA membrane; b) high porosity of the floating units provided by freeze-drying process. The designed floating units prolonged significantly the GRT of the units (2-9 h) according to the feeding conditions and increased the relative bioavailability of drugs (50-80%) having an absorption window in the intestine.

2. Innovative aspect of the product

Oral administration has always kindled great interest for the high compliance of the patient even if problems connected to the physiology of gastro-intestinal tract can arise. The optimisation of this administration represents a very interesting approach from both an application and production point of view. Rapid and variable GRT of a drug dosage form could result in incomplete drug release from the device above the absorption zone leading to diminished efficacy of local gastric agents as well as diminished and less reproducible bioavailability of drugs either absorbed mainly in the stomach or with an absorption window in the upper intestinal tract. Therefore, prolonged GRT combined with a modulated drug release in the stomach could provide increased and more reproducible bioavailability. By comparison with a few commercial products, the developed floating device is multiparticulate and it can offer a simple production technology using natural materials as well as lack of buoyancy lag time which could limit the device efficiency.

3. Main advantages of the offer

The designed multiple-unit floating system allows to increase and make more reproducible the gastric residence time of orally administered drugs. The floating units are able to buoyant immediately and for a

long time in the stomach with a consequent slow delivery of the drug. The units are obtained from natural, non toxic materials, and they can be handled in aqueous fluid with a simple and rapid technique of extrusion. Different active ingredients can be incorporated in both solution and dispersed state without compromise the device properties.

The units can be easily administered (4 mm of diameter) and they allow to obtain different dosage levels by changing both the drug amount and the unit number. Also, they can transport different drugs included separately into the units. Some examples of application of this product involved: antiacids, antiulcers, gastric protectants, furosemide, captopril, antibiotics for Helicobacter pylori treatment, etc.

4. Technology key words

Floating system, alginate, oral route

5. Current Stage of Development

Air-compartment device concluded. Porous device in development phase

6. Intellectual Property Rights

The product is not covered by patent

Technical and scientific publications

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