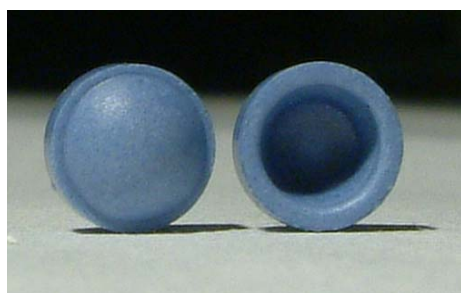


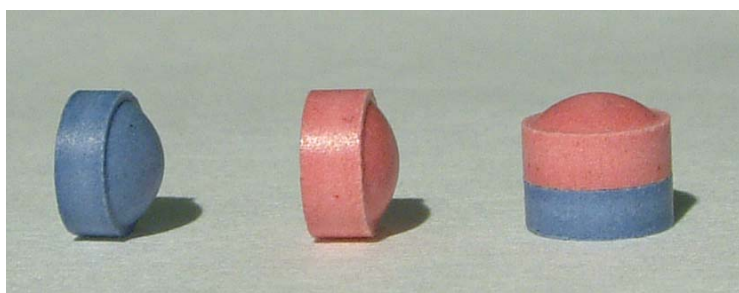
Modular drug delivery system for time and space drug release control

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The University of Parma developed an innovative drug delivery platform based on a modular technology. Release modules, consisting in swellable polymeric matrix, are assembled together in a firm structure to form the drug delivery system. In dependence on modules assemblage, different system configurations can be obtained. The modular approach makes possible to administer different drugs at the same time at different rate and in a selected environment.



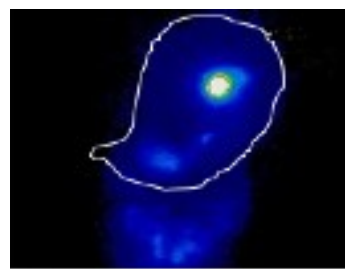
Release module



Piled configuration



Void configuration



In vivo Floating of the system in void configuration

1. Description of the product

This delivery system is based on tablets (modules) made of swellable polymer for controlling the release rate. The module in its typical shape is a cylindrical tablet having one concave and one convex base, designed for allowing the assembling by inserting the convex base into concave base. This shape allows to put together several modules in order to create different assembled release systems. The assemblies can be obtained engaging the bases of the modules using glue or ultrasound application. Recently, a solution was discovered for assembling through interlocking of modules having a rim on concave base that allows the concave to concave base clicking. Piled configurations can be obtained by staking two or more modules convex face into concave base. A peculiar assembly obtained by fitting the concave base with the concave base of another module makes feasible the construction of a floating system able to keep the drug release into the stomach. This configuration is characterized by an empty space between two modules that make the assembly floating. This cavity could also be utilized as reservoir to delivery drugs in the colon.

2. Innovative aspect of the product

The increasing use of pharmacological therapies connected to chronic pathologies (above all for older people) stressed the relevance of poly-drug therapy. In these cases the contemporary administration of different drugs is necessary for fighting efficaciously the disease and preventing side effects. The assembled module is a response to this need since the dosage form includes in one administration dose all the

substances required by the patient. Different drugs can be administered in one pharmaceutical dosage form at different rates by introducing them in different modules.

The highest innovation is obtained with the possibility to construct a gastro-retentive system based on the flotation of modules assembled. In fact, due to the design of the module shape, an internal void space is obtained from the assemblage concave to concave. This void space determines the immediate flotation of the system in vitro and in vivo.

3. Main advantages of the offer

The technology, called Dome Matrix, is an alternative to the existing oral drug delivery technologies. This product is of interest for pharmaceutical industries which manufacture and commercialize prolonged release solid dosage forms. The release platform is directed to firms dealing with production of traditional and biotechnological drugs in dosage forms for an innovative controlled release. The technology proposed constitutes an effective answer to the necessities to have versatility in drug release kinetics, modulation of dose administered and association of different drugs in one modular system.

Since the technology provides a time and space controlled release system, it can be applied also in agricultural, industrial and consumer applications.

The release rate change is obtained by increasing number of the modules, due to the change the volume/surface ratio. In case two concave faces are soldered, an empty "camera", which determines an immediate floating of the system, is obtained. Systems with this configuration guarantee the permanence of the drugs in the stomach for longer time improving the absorption of the drug at gastric level or increasing the bioavailability for drugs having narrow absorption window.

The empty camera can be filled with a additional drug that must be protect from gastric juice or delivered to the colon.

The industrial advantage is the renewal of old products in a new dosage form. Moreover, Dome Matrix technology makes possible to administer two or more drug with different kinetics in one assembly for a once a day administration.

4. Technology key words

DOME MATRIX®, Drug delivery, Gastro-retentive, Assembly, Once a day, Interlocking

5. Current Stage of Development

Industrial development in progress – Tested in laboratory

6. Intellectual Property Rights

The product of the research is covered by patent.

Technical and scientific publications

Assemblage of novel release modules for the development of adaptable drug delivery systems. Losi E, Bettini R, Santi P, Sonvico F, Colombo G, Lofthus K, Colombo P, Peppas NA. J Control Release 111 (2006) 212-8.

New modules, new assemblage kits and new assemblies for the controlled release of substances. P. Colombo, P. Santi, Bettini R, Strusi O.L, Sonico F, Colombo G. PCT/EP/2006/011661, December 5, 2006

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