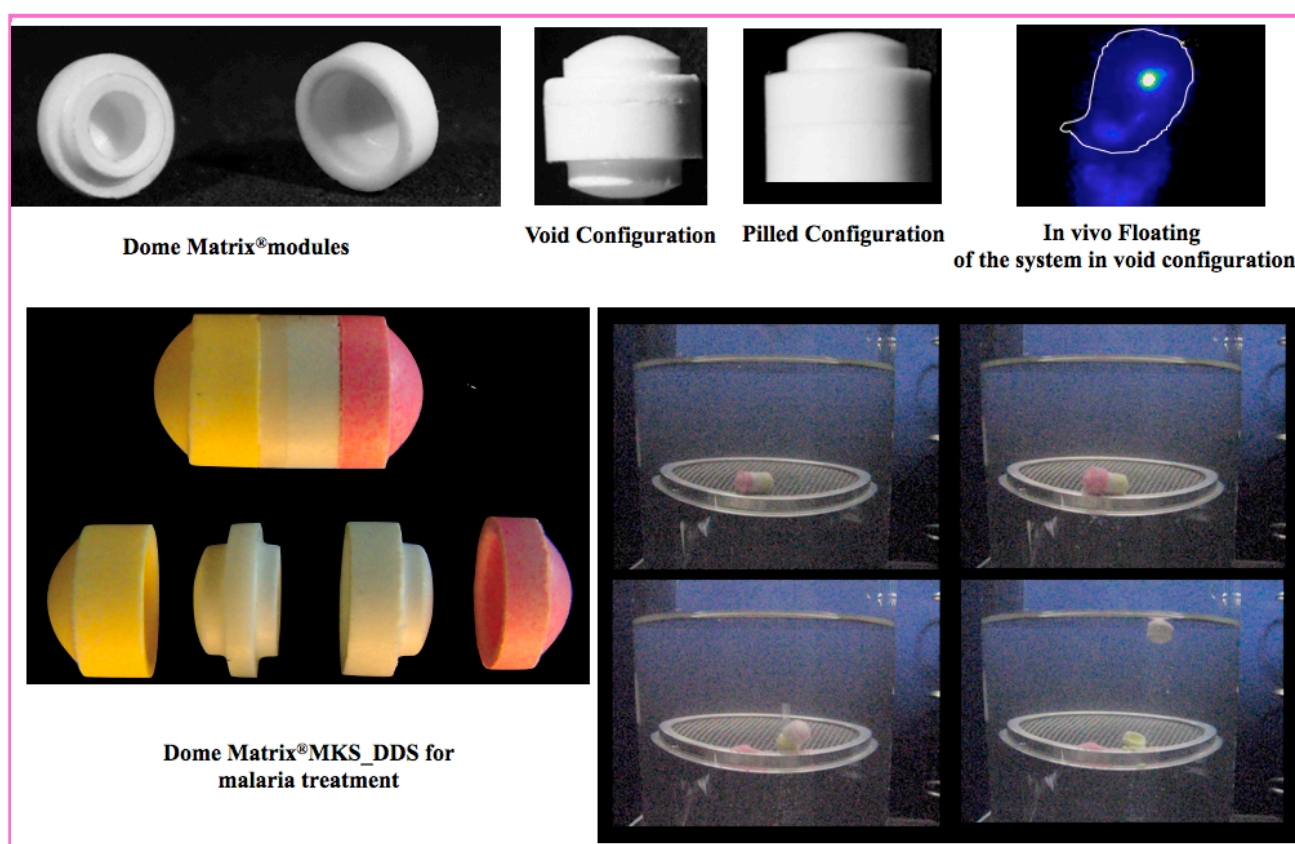


Modular drug delivery systems for time and space release control

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An innovative drug delivery platform based on a modular technology have been developed at the University of Parma. Release modules, consisting in swellable polymeric matrix have been assembled in a firm structure to form the drug delivery system. In dependence on the module assemblage way, 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 site.



1. Description of the product

This delivery modules are tablets for immediate or prolonged release such as inert or swellable matrices. 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. Putting together two or more modules it creates assembled release systems. Assemblies can be obtained through interlocking of modules in piled configurations 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 base makes feasible the construction of a floating system able to promote 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. Innovation aspects of the product

The multi-drug pharmacological therapies connected to chronic pathologies stressed the relevance of poly-drug therapy. In these situations, the contemporary administration of different drugs is necessary for

efficaciously fighting the disease and preventing side effects. The assembled module technology 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 obtained was the gastro-retentive behavior based on the flotation of modules assembled concave-to-concave. In vivo studies confirmed the gastroretention ability of Dome Matrix® void configuration. In the human stomach, the system stayed for periods of time ranging from 2.5 to 5.0 h, depending on the food regimen and the sex of the subject.

3. Main advantages

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 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 could be applied also in agricultural, industrial and consumer applications.

Release rate change is obtained by increasing number of the modules, due to the change the volume/surface ratio of the system. In case two concave faces are interlocked, an empty "camera" determines the immediate floating of the system. Systems in 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-retention, Module assembling, Once a day, Interlocking

5. Current Stage of Development

Industrial development in progress – Tested in laboratory

6. Intellectual Property Rights

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