ChronoCap™: a Novel Pulsatile Delivery System

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A novel capsular device intended for oral pulsatile (time-controlled) release of differing drug formulations is proposed. The system is prepared by injection-molding of powder blends based on swellable/erodible hydrophilic polymers (GRAS materials). The resulting capsule shells are capable of delaying the liberation of the conveyed drug for a programmed time period through their slow interaction with the gastrointestinal fluids. Perfectly matching bodies and caps with varying thickness can be obtained, thus ideally providing a “library” of devices able to yield diverse \textit{in vivo} performances. Moreover, they can be filled with solid or liquid preparations (e.g. powders, tablets, pellets, solutions, dispersions). Peculiar advantages are the chance of undergoing an independent pharmaceutical development regardless of filling (drug formulation), the scalability of the manufacturing process and a remarkable versatility.

1. Description of the product

The ChronoCap™ technology relates to an oral capsular device intended for pulsatile (time-controlled) release of drugs. Such capsules are prepared from hydrophilic polymeric materials that undergo a glassy-rubbery transition when exposed to aqueous fluids, thereby delaying the release of the contents for a programmable drug for a programmed time period following administration. The lag time that precedes the onset of release can be modulated as a function of the thickness and composition of the capsule shell. ChronoCap™ devices can be filled just like hard gelatin capsules and may convey solid (powders, capsules, tablets, granulates, pellets, micro- or nano-particles), semi-solid or liquid drug formulations.

The ChronoCap™ can optionally be coated with gastro-resistant polymers thus being adapted to a time-dependent colon delivery system. Colonic release is of high interest not only for the therapy or prevention of pathologies that affect the large intestine (ulcerative colitis, Crohn’s disease, colorectal adenocarcinoma, microflora disorders), but also for pharmacological treatments that require a systemic absorption of the drug.
2. Innovative aspect of the product
The ChronoCap™ can be manufactured in different types and sizes of bodies and caps with varying thickness and composition, which ideally provides a “library” of devices able to yield a range of in vivo performances. Moreover, the ChronoCap™ can be filled with solid as well as liquid preparations (e.g. powders, tablets, pellets, solutions, dispersions). Due to its nature of “functional container”, the product could undergo an independent pharmaceutical development regardless of the filling.

3. Main advantages of the offer
The ChronoCap™ provides a tool for the delivery of drugs to be used for therapies in which a lag phase is desired after administration. In particular, this technology is exploitable in those cases in which disease symptoms are predominantly experienced during the night or early morning hours. Examples of such pathologies are bronchial asthma, with more frequent attacks during the night hours, sleep disorders such as early morning awakening, rheumatoid arthritis and cardiovascular disease with prevailing incidence in the early morning. ChronoCap™ devices would in these instances allow the release and absorption of the active ingredient to be aligned with the appearance of the symptoms, thus enhancing the efficacy and safety of the therapy.

The ChronoCap™ delivery technology is reasonably expected to meet general feasibility and scale-up criteria and to involve a relatively limited regulatory burden.

4. Technology key words
ChronoCap™, time- and site-controlled delivery systems, colon delivery, pulsatile release

5. Current Stage of Development
Available for demonstration

6. Intellectual Property Rights
Patents pending on specific formulation aspects (PCT WO2010/009891 A1, Trademark MI2011C001267)

Technical and scientific publications


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