The inner coat of the drug delivery system is additionally surrounded by an outer coat that contains additional amounts of a desired ingredient. When the delivery device enters the gastrointestinal tract, the outer coat releases the desired ingredient contained therein and disintegrates, exposing the inner coat. By controlling parameters in the device, such as the core material, carrier material in the coating, and particulate matter, the location of release of both drug pulses can be controlled.

The afore mentioned drug delivery systems, while effective in delaying release of a drug to specific parts of the gastrointestinal tract such as, for example, the small intestine or the colon, were found to be ineffective in providing a drug in a short pulse after a certain period of time, irrespective of the presence in a specific body compartment.

There is a clear need for a drug delivery system that releases a drug after a predetermined period of time (a lag time) following administration of the drug delivery system. In addition, there is a need for a drug delivery device that combines a drug delivery system that is effective in delivering a drug in a short pulse after a predetermined period of time with a drug delivery system that provides immediate release of a drug at an earlier point in time after administration, preferably in the oral cavity.

Summary

In one aspect, the present invention provides a time controlled, immediate release drug delivery system for oral administration of a first active ingredient to a subject in need thereof, the system comprising

a core comprising 10-60% (w/w) microcrystalline cellulose, 20-70% (w/w) of an inorganic salt as a filler, and 0.1-30 % (w/w) of a first active ingredient; wherein the core further comprises a cross-linked sodium carboxy methylcellulose; and wherein microcrystalline cellulose and crosslinked sodium carboxy methylcellulose are present in a ratio of between about 6:1 (w/w) to 14:1 (w/w), and

a first coating surrounding the core, said first coating comprising a hydrophobic polymer and a hydrophilic substance.

In another aspect, the present invention provides a dual drug delivery device, comprising the time controlled, immediate release drug delivery system as defined herein, wherein the first coating of the drug delivery system is surrounded by a second coating comprising a second active ingredient.

In yet another aspect, the present invention provides a tablet for sublingual administration of an active ingredient said tablet comprising a core, and a coating (outer coating) on the exterior surface of said core and optionally a coating that separates said outer coating from said core (separation coating), wherein said outer coating comprises a mixture of

- an active ingredient in amorphous form in an amount of between about 0.1 – 10 mg;
- a coating polymer in an amount of between about 0.25 – 25 mg; and
- water in an amount of between about 0.0 – 10% w/w of the outer coating; and wherein said core comprises 10-60% (w/w) microcrystalline cellulose, 20-70% (w/w) of an inorganic salt as a filler, and 0.1-30 % (w/w) of a first active ingredient; wherein the core further comprises a cross-linked sodium carboxy methylcellulose; and wherein microcrystalline cellulose and crosslinked sodium carboxy methylcellulose are present in a ratio of between about 6:1 (w/w) to 14:1 (w/w).

In yet another aspect, the present invention provides the use of a device as defined herein or a tablet as defined herein, in the preparation of a medicament for treatment of male or female: sexual dysfunction, desire dysfunction, or erectile dysfunction, and preferably for use in the treatment of Hypoactive Sexual Desire Disorder.

In yet another aspect, the present invention provides a time controlled, immediate release drug delivery system for oral administration of a first active ingredient to a subject in need thereof, the system comprising

a core comprising 10-60% (w/w) cellulose, 20-70% (w/w) of a filler selected from an organic and/or an inorganic salt, and 0.1-30 % (w/w) of a first active ingredient, and

a first coating surrounding the core, said first coating comprising a hydrophobic polymer and a hydrophilic substance; wherein the hydrophobic polymer is ethylcellulose and the hydrophilic substance is lactose; and wherein the mass ratio of ethylcellulose and lactose is about 1:1.

Detailed Description

Therefore, the invention provides a time controlled, immediate release drug delivery system for oral administration of a therapeutically effective amount of a first active ingredient to a subject in need thereof, comprising a disintegrating core comprising cellulose, a filler selected from an organic and/or an inorganic salt, and a first active ingredient, said system further comprising a first coating surrounding the core, said first coating comprising