Claims

1. 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.

2. The system according to claim 1, wherein said filler is an inorganic salt.

3. The system according to claim 1 or claim 2, wherein said cellulose is microcrystalline cellulose.

4. The system according to any one of claims 1-3, wherein said inorganic salt is anhydrous dibasic calcium phosphate.

5. The system according to any of claims 1-4, wherein said delivery system is a tablet.

6. The system according to any of the previous claims wherein said core additionally comprises a water-insoluble gel-forming disintegrant comprising cross-linked sodium carboxy methylcellulose, sodium starch glycolate and/or cross-linked polyvinylpyrrolidone.

7. The system according to any of the previous claims wherein the hydrophobic polymer of the first coating is ethylcellulose.

8. The system according to any of the previous claims wherein the hydrophilic substance of said first coating is a water insoluble hydrophylic substance.

9. The system according to claim 8, wherein first coating contains pores prior to exposure to an aqueous liquid.

10. The system according to any of claims 1-7, wherein the hydrophilic substance of said first coating is a water soluble ~~hydrophylic~~ hydrophilic substance.

11. The system according to claim 10, wherein the water soluble ~~hydrophylic~~ hydrophilic substance forms pores in the hydrophobic polymer upon exposure to an aqueous liquid.

12. The drug delivery system according to claim 1, 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.

13. The drug delivery system according to claim 1, the core further comprising 0.5-6% (w/w) of one or more of a water-insoluble, gel-forming disintegrant.

14. The drug delivery system according to claim 13, wherein the water-insoluble, gel-forming disintegrant is cross-linked sodium carboxymethyl cellulose.

15. The drug delivery system according to claim 3, wherein the filler is anhydrous dicalcium phosphate; and wherein the core further comprises a crosslinked sodium carboxy methylcellulose and magnesium stearate; 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).

~~12~~16. The system according to any of the previous claims wherein the first active ingredient is selected from the group consisting of a PDE5 inhibitor, a 5HT1a receptor agonist, and a neutral endopeptidase inhibitor.

~~13~~17. The system according to claim ~~12~~ 16 wherein the PDE5 inhibitor comprises sildenafil.

~~14~~18. The system according to claim ~~12~~ 16 wherein the 5HT1a receptor agonist comprises buspirone.

~~15~~19. A dual drug delivery device, comprising the time controlled, immediate release drug delivery system according to any one of claims 1-~~14~~18, wherein the first coating of the drug delivery system is surrounded by a second coating comprising a second active ingredient.

~~16~~20. The device according to claim ~~15~~19, wherein the second coating comprises hydroxypropylmethylcellulose.

~~17~~21. The device according to claim ~~15~~ 19 or claim ~~16~~20, wherein the second coating provides for immediate delivery of the second active ingredient in the mouth.

~~18~~22. The device according to any of claims ~~15~~19-21-~~17~~, wherein the second active ingredient is testosterone or a functional analogue of testosterone.

~~19~~23. The device according to any of claims ~~15~~19-~~18~~22, wherein the second coating comprises a cyclodextrin, or a derivative or polymer thereof.

~~20~~24. The device according to any one of claims ~~15~~19-~~19~~23, wherein the second coating further comprises a flavouring compound.

~~21~~25. The device according to claim ~~20~~24, wherein presence of a flavour indicates that the device is to be held in the mouth.

~~22~~26. The device according to any one of claims ~~15~~19-~~21~~25, wherein an outer surface of the second coating is rougher ~~that~~ than an outer surface of the first coating.

~~23~~27. A method for preparing a dual delivery drug device comprising a first and a second coating, wherein a roughness of an outer surface of the first coating differs from a roughness of an outer surface of the second coating.

~~24~~28. 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) cellulose, 20-70% (w/w) of a filler selected from an organic and/or inorganic salt, and 0.1-30 % (w/w) of a first active ingredient.

25. A tablet according to claim 24, wherein said mixture comprises said active ingredient in an amount of between about 0.2 – 5,0 mg; said coating polymer in an amount of between about 0.5 – 12,5 mg; and water in an amount of between about 0.0 – 5% w/w of the outer coating.

26. A tablet according to claim 24, wherein said mixture further comprises a cyclodextrin or a polyvinylpyrolidone, or a combination thereof in an amount of between 0.25 – 25 mg.

27. A tablet according to claim 25, wherein said mixture further comprises a cyclodextrin or a polyvinylpyrolidone, or a combination thereof in an amount of between 0.5 – 12,5 mg.

28. A tablet according to any one of claims 24-27, comprising a separation coating that separates said outer coating from said core.

29. A tablet according to any one of claims 24-28, wherein said core and said optional separation coating has a volume of between 50 – 1000 mm^3.

~~30. A tablet according to any one of claims 24-29, wherein said core comprises a cellulose, an inorganic salt and a first active ingredient.~~

~~31~~34. A tablet according to any one of claims ~~24~~27-~~30~~33, wherein said separation coating comprises a hydrophobic polymer and a hydrophilic substance.

~~32~~35. A tablet according to any one of claims ~~24~~27-~~31~~34, wherein said mixture of said outer coating further comprises a sweetener and/or a flavor.

~~33~~36. A tablet according to any one of claims ~~24~~28-~~32~~35, wherein said separation coating is a pH-independent coating.

~~34~~37. A tablet according to any one of claims ~~24~~28-~~32~~35, wherein said separation coating is a pH-dependent coating, preferably an acid soluble coating or an enteric coating.

~~35. A method for administering a active ingredient to an individual said method comprising providing the individual in need thereof with a tablet according to any one of claims 24-34, wherein said individual holds the tablet in the mouth for between 10 seconds and 5 minutes and wherein said individual subsequently swallows said tablet.~~

~~36~~38. ~~A~~ Use of a device according to any one of claims 15-22 or a tablet according to any one of claims ~~24~~28-~~34~~37, ~~for use in the~~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.

~~37~~39. A dual drug delivery device according to any one of claims 15-22~~ or 36~~, the core comprising:

between 100 mg and 150 mg of ~~Pharmacel pH102~~microcrystalline cellulose;

between 100 mg and 150 mg of DicalciumPhosphate 0 aq;

between 25 mg and 100 mg of Sildenafil citrate;

between 10 mg and 20 mg of Croscarmellose;

between 1 mg and 2 mg of Magnesiumstearate;

the first coating comprising:

between 5 mg and 20 mg of ~~Ethocel 20~~ethylcellulose;

between 5 mg and 20 mg of microcrystalline cellulose with a nominal particle size of about 20 micron and a moisture less than 5.0 %~~Avicel pH 105~~;

the second coating comprising:

between 1 mg and 2 mg of hydroxypropylmethylcellulose (HPMC) 5cps;

between 2 mg and 3.5 mg of HydroxyPropyl B-cyclodextrin; and

between 0.1 mg and 1 mg of Testosterone.

~~38~~40. A dual drug delivery device according to any one of claims 15-22~~ or 36~~, the core comprising:

between 50 mg and 150 mg of microcrystalline cellulose~~Pharmacel pH 200~~;

between 150 mg and 250 mg of DicalciumPhosphate 0 aq;

between 1 mg and 20 mg of Buspirone Hydrochloride;

between 10 mg and 20 mg of Croscarmellose;

between 1 mg and 10 mg of Magnesiumstearate;

the first coating comprising:

between 5 mg and 20 mg ~~Ethocel 20~~ethylcellulose;

between 10 mg and 50 mg of microcrystalline cellulose with a nominal particle size of about 20 micron and a moisture less than 5.0 %~~Avicel pH 105~~;

the second coating comprising:

between 1 mg and 2 mg of HPMC 5cps

between 2 mg and 3.5 mg of HydroxyPropyl B-cyclodextrin; and

between 0.1 mg and 1 mg of Testosterone.

~~39~~41. A dual drug delivery device according claim ~~37~~39 or 40~~38~~, wherein the second coating further comprises between 1 mg and 2 mg peppermint- oil and between 0.5 mg and 1.5 mg of aspartame.