

WHAT IS CLAIMED IS:

1. A multi-drug delivery system comprising
a first capsule comprising:
a first capsule body comprising a first interior;
a first tablet within the first interior, the first tablet comprising a first drug; and
a second tablet within the first interior, the second tablet comprising at least a second drug different from the first drug, and a third drug different from the first and second drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within a patient; and
a second capsule, co-packaged with the first capsule, comprising:
a second capsule body comprising a second interior; and
a third tablet within the second interior, the third tablet comprising the first drug,
wherein using USP apparatus 2 at 50 rpm, pH 6.8, and $37.5 \pm 0.5^\circ\text{C}$, at least 75% of the first drug in the first tablet dissolves after 60 minutes and at least 70% of the second and third drugs in the second tablet dissolve after 30 minutes.
2. The multi-drug delivery system in accordance with Claim 1, wherein the first tablet comprises elagolix.
3. The multi-drug delivery system in accordance with Claim 1 or 2, wherein the first tablet comprises between about 175 mg to about 325 mg of elagolix and the second tablet comprises between about 0.75 mg and about 1.25 mg of estradiol.

4. The multi-drug delivery system in accordance with claim 3, wherein the second tablet further comprises between about 0.1 mg and about 1 mg of norethindrone acetate.

5. The multi-drug delivery system in accordance with claim 3, wherein after about 15 minutes, the release of estradiol is equal to or greater than 70%.

6. The multi-drug delivery system in accordance with Claim 1, wherein the first capsule is marked with a first identifier and the second capsule is marked with a second identifier different from the first identifier such that the first capsule and the second capsule are visually distinguishable.

7. The multi-drug delivery system in accordance with Claim 6, wherein the first identifier is configured to indicate the first capsule is intended for administration within a first time window in the day, and the second identifier is configured to indicate the second capsule is intended for administration within a second time window in the day different from the first time window.

8. The multi-drug delivery system in accordance with Claim 7, wherein the first identifier is configured to indicate the first capsule is intended for administration at the first time window that is before noon, and the second identifier is configured to indicate the second capsule is intended for administration at the second time window that is after noon.

9. The multi-drug delivery system in accordance with any of Claims 6-8, wherein the first identifier is a first color included on the first capsule, and the second identifier is a second color included on the second capsule.

10. The multi-drug delivery system in accordance with any of Claims 1-9 further comprising a package comprising a plurality of compartments configured to house the first capsule and the second capsule.

11. The multi-drug delivery system in accordance with Claim 10, wherein the package comprises a blister card that defines the plurality of compartments, wherein the first capsule and the second capsule housed in the plurality of compartments are accessible by puncturing a seal in the blister card.

12. The multi-drug delivery system in accordance with Claim 10 or 11, wherein the package comprises information printed thereon related to when to administer the first capsule and the second capsule to the patient.

13. The multi-drug delivery system in accordance with Claim 10, wherein the blister card comprises a first row of the plurality of compartments and a second row of the plurality of compartments, wherein the first capsule is housed in the first row, wherein the second capsule is housed in the second row, and wherein the first row and the second row are visually distinct.

14. A capsule for use in delivering drugs to a patient, the capsule comprising:

a capsule body comprising an interior;

a first tablet within the interior, the at least one first tablet comprising a first drug; and

a second tablet within the interior, the second tablet comprising at least a second drug different from the first drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the capsule body within the patient,

wherein using USP apparatus 2 at 50 rpm, pH 6.8, and $37.5 \pm 0.5^\circ\text{C}$, at least 75% of the first drug in the first tablet dissolves after 60 minutes and at least 70% of the second drug in the second tablet dissolves after 30 minutes.

15. The capsule in accordance with Claim 14, wherein the first tablet comprises between about 175 mg and about 325 mg of elagolix and the second tablet comprises between about 0.75 mg and about 1.25 mg of estradiol.

16. The capsule in accordance with claim 15, wherein the second tablet further comprises between about 0.1 mg and about 1.0 mg of norethindrone acetate.

17. The capsule in accordance with claim 15, wherein after 16 minutes, the release of estradiol is equal to or greater than 70%.

18. The capsule in accordance with Claim 14, wherein the capsule body is oblong to define a longitudinal axis, wherein the at least one first tablet and the second tablet are arranged in a serial relationship along the longitudinal axis within the interior.

19. The capsule in accordance with Claim 14, wherein the at least one first tablet and the second tablet are distinct tablets that have been formed separately from each other and then secured within the interior.

20. The capsule in accordance with Claim 14, wherein the capsule body does not contain drugs in powder form.

21. The capsule in accordance with Claim 14, wherein the capsule body does not include a barrier extending between the first tablet and the second

tablet, and wherein the first tablet and the second tablet are not bonded together within the interior.

22. The capsule in accordance with Claim 14, wherein the second tablet comprises the second drug and a third drug that are both configured to have a dissolution rate of greater than about 80 percent within the first 30 minutes of administration using USP apparatus 2 at 50 rpm, pH 6.8, and $37.5 \pm 0.5^\circ\text{C}$.

23. The capsule in accordance with Claim 14, wherein the first capsule comprises gelatin.

24. A method of delivering drugs to a patient, the method comprising:
delivering a first capsule to the patient, wherein the first capsule includes:
a first capsule body including a first interior;
a first tablet within the first interior, the first tablet including a first drug; and
a second tablet within the first interior, the second tablet including at least a second drug different from the first drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within the patient; and
delivering a second capsule, co-packaged with the first capsule, to the patient after a predetermined amount of time has elapsed after administration of the first capsule, wherein the second capsule includes:
a second capsule body including a second interior; and
a third tablet within the second interior, the third tablet including the first drug.

25. The method accordance with Claim 24, wherein the first tablet comprises between about 175 and 325 mg of elagolix and the second tablet

comprises between about 0.75 mg and 1.25 mg of estradiol and between about 0.1 mg and 1.0 mg of norethindrone.

26. The method in accordance with claim 24, wherein after 20 minutes, the release of estradiol is equal to or greater than 70%.

27. The method in accordance with Claim 24, wherein delivering a second capsule comprises delivering the second capsule at least 5 hours after administration of the first capsule.

28. The method in accordance with Claim 24, wherein delivering the first capsule comprises delivering the first capsule at a first time window in the day that is before noon, and wherein delivering a second capsule comprises delivering the second capsule at a second time window in the day that is after noon.

29. The method in accordance with Claim 24 further comprising providing a package comprising a plurality of compartments configured to house the first capsule and the second capsule therein.

30. The method in accordance with Claim 29 further comprising housing a plurality of first capsules and a plurality of second capsules within the package, wherein the number of first capsules and the number of second capsules housed within the package are each a multiple of the number of days in a week.

31. A multi-drug tablet having a first tablet and a second tablet coated on the first tablet.

32. The multi-drug tablet of claim 31, wherein the second tablet is positioned in the center of the first tablet.

33. The multi-drug tablet of claim 32, further comprising crospovidone.

34. A medication container assembly comprising:
a first set of a plurality of compartments each compartment configured to support a first capsule;
a second set of a plurality of compartments each compartment configured to support a second capsule co-packaged with the first capsule;
wherein, the first capsule comprises a first interior;
a first tablet within the first interior, the first tablet comprising a first drug; and
a second tablet within the first interior, the second tablet comprising at least a second drug different from the first drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within a patient; and
the second capsule comprises a second capsule body comprising a second interior, and a third tablet within the second interior, the third tablet comprising the at least one drug selected from the group consisting of: the first drug, the second drug, or a third drug.

35. A multi-drug capsule comprising:
a first tablet, the first tablet comprising a first drug;
a second tablet, the second tablet comprising at least a second drug different from the first drug, and a third drug different from the first and second drug,
wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the capsule within a patient;

wherein using USP apparatus 2 at 50 rpm, pH 6.8, and $37.5 \pm 0.5^\circ\text{C}$, at least 75% of the first drug in the first tablet dissolves after 60 minutes and at least 70% of the second and third drugs in the second tablet dissolve after 30 minutes.

36. The multi-drug capsule in accordance with Claim 35, wherein the first tablet comprises elagolix.

37. The multi-drug capsule in accordance with Claim 35 or 36, wherein the first tablet comprises between about 175 mg to about 325 mg of elagolix and the second tablet comprises between about 0.75 mg and about 1.25 mg of estradiol.

38. An oral multi-drug capsule composition comprising:

- (a) 300 mg of free acid equivalent of elagolix;
- (b) 1 mg of estradiol; and
- (c) 0.5 mg of norethindrone acetate;

wherein, following administration of a single dose of the composition to healthy adult subjects results in a mean peak concentration (C_{max}) for said elagolix of about 1218.4 ng/mL to about 2185 ng/mL;

a mean peak concentration (C_{max}) for said estradiol of about 0.0424 ng/mL to about 0.0775 ng/mL;

a mean peak concentration (C_{max}) for said norethindrone acetate of about 4.56 ng/mL to about 8.0 ng/mL;

a mean Area Under the Curve ($\text{AUC}_{(t)}$) for said elagolix of about 3293.6 ng.hr/mL to about 5892.5 ng.hr/mL;

a mean Area Under the Curve ($\text{AUC}_{(t)}$) for said estradiol of about 0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and

a mean Area Under the Curve ($\text{AUC}_{(t)}$) for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125 ng.hr/mL.

39. An oral multi-drug capsule composition comprising:

- (a) 300 mg of free acid equivalent of elagolix;
- (b) 1 mg of estradiol which is administered once daily; and
- (c) 0.5 mg of norethindrone acetate;

wherein administration of a single dose of the composition to healthy adult subjects results in a mean peak concentration, C_{max} for said elagolix of about 1218.4 ng/ml to about 2185 ng/mL;

a mean peak concentration, C_{max} for said estradiol of about 0.0424 ng/ml to about 0.0775 ng/ml; and

a mean peak concentration, C_{max} for said norethindrone acetate of about 4.56 ng/ml to about 8.0 ng/ml.

40. The oral multi-drug capsule composition of claim 39, wherein

a mean Area Under the Curve, $AUC_{(t)}$ for said elagolix of about 3296.6 ng.hr/mL to about 5892.5 ng.hr/mL;

a mean Area Under the Curve, $AUC_{(t)}$ for said estradiol of about 0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and

a mean Area Under the Curve, $AUC_{(t)}$ for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125 ng.hr/mL.

41. An oral multi-drug capsule composition comprising:

- (a) 300 mg of free acid equivalent of elagolix;
- (b) 1 mg of estradiol; and
- (c) 0.5 mg of norethindrone acetate;

further wherein administration of a single dose of the composition to healthy adult subjects results in

a mean Area Under the Curve, $AUC_{(t)}$ for said elagolix of about 3293.6 ng.hr/mL to about 5892.5 ng.hr/mL;

a mean Area Under the Curve, $AUC_{(0)}$ for said estradiol of about 0.0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and

a mean Area Under the Curve, $AUC_{(0)}$ for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125 ng.hr/mL.

42. The oral multi-drug capsule composition of claim 41, wherein administration of the composition to healthy adult subjects results in

a mean peak concentration, C_{max} for said elagolix of about 1218.4 ng/mL to about 2185 ng.hr/mL;

a mean peak concentration, C_{max} for said estradiol of about 0.0424 ng.hr/mL to about 0.0775 ng/mL ng/mL; and

a mean peak concentration, C_{max} for said norethindrone acetate of about 4.56 ng.hr/mL to about 8.0 ng/mL.

43. An oral multi-drug capsule composition comprising:

(a) 300 mg of free acid equivalent of elagolix;

(b) 1 mg of estradiol; and

(c) 0.5 mg of norethindrone acetate;

wherein using USP apparatus 2 at 50 rpm, pH 6.8, and $37.5 \pm 0.5^\circ\text{C}$, at least 75% of the first drug in the first tablet dissolves after 60 minutes and at least 70% of the second and third drugs in the second tablet dissolve after 30 minutes.

44. A method of safely treating heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in a pre-menopausal female patient comprising once daily oral administration to said patient of:

(a) 300 mg of free acid equivalent of elagolix;

(b) 1 mg of estradiol; and

(c) 0.5 mg of norethindrone acetate,

wherein said method results in a mean C_{max}

for said elagolix of about 1218.4 ng.hr/mL to about 2185 ng/mL;
for said estradiol of about 0.0424 ng/mL to about 0.0775 ng/mL;
for said norethindrone acetate of about 4.56 ng/mL to about 8.0 ng/mL, and
a mean $AUC_{(t)}$

for said elagolix of about 3293.6ng.hr/mL to about 5892.5 ng.hr/mL;
for said estradiol of about 0.0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and
for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125
ng.hr/mL, and

wherein, after a treatment duration of about 6 months, said patient achieves equal to or greater than about 2 g/dL increase in hemoglobin as compared to baseline where the patient did not receive elagolix, estradiol, and norethindrone.

45. A capsule for use in delivering drugs to a patient, the capsule comprising:

a capsule body comprising an interior;

a first tablet within the interior, the at least one first tablet comprising a first drug; and

a second tablet within the interior, the second tablet comprising at least a second drug different from the first drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the capsule body within the patient,

wherein using USP apparatus 1 at 100 rpm, pH 6.8, and $37.5 \pm 0.5^\circ\text{C}$, at least 75% of the first drug in the first tablet dissolves after 45 minutes and at least 90% of the second and third drugs in the second tablet dissolve after 30 minutes.

46. An oral multi-drug capsule composition that is bioequivalent to any of the composition of claims 31-34, 36-45.

47. A method of delivering co-packaged drugs to a patient for oral use, the method comprising:

delivering a first capsule to the patient, wherein the first capsule includes:

a first capsule body including a first interior;

a first tablet within the first interior, the first tablet including a first drug; and

a second tablet within the first interior, the second tablet including at least a second drug different from the first drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within the patient; and

delivering a second capsule, co-packaged with the first capsule, to the patient after a predetermined amount of time has elapsed after administration of the first capsule, wherein the second capsule includes:

a second capsule body including a second interior; and

a third tablet within the second interior, the third tablet including the first drug.