Claims :-

1. A pharmaceutical composition suitable for oral administration, wherein the composition comprises:

a) a core comprising a polymer matrix and phenylephrine or a pharmaceutically acceptable salt thereof, wherein the matrix completely erodes within 4-12 hours after ingestion; and

b) an erodible layer, optionally comprising phenylephrine or a pharmaceutically acceptable salt thereof;

wherein upon ingestion of the composition by a subject at least a portion of phenylephrine is absorbed in the colon of the subject.

2. The pharmaceutical composition of Claim 1, wherein at least 5% by weight of phenylephrine or a pharmaceutically acceptable salt thereof is absorbed in the colon of the subject.

3. The pharmaceutical composition according to Claim 1, wherein the core is in solid, liquid, gel or semi-solid form.

4. The pharmaceutical composition according to Claim 1, wherein the core comprises one or more pellets comprising phenylephrine or a pharmaceutically acceptable salt thereof.

5. The pharmaceutical composition according to Claim 4, wherein one or more pellets have an erodible pellet coating on the surface of said pellet(s).

6. The pharmaceutical composition according to Claim 5, wherein the erodible pellet coating comprises a pH-sensitive polymer or a colon-specific polymer. 7. The pharmaceutical composition according to Claim 1, wherein the core further comprises a penetration enhancer.

8. The pharmaceutical composition according to Claim 1, wherein the core is exposed by erosion of the erodible layer at least 5 hours after ingestion by the subject.

9. The pharmaceutical composition according to Claim 8, wherein the core is exposed by erosion of the erodible layer at least 8 hours after ingestion by the subject.

10. The pharmaceutical composition according to Claim 1, wherein the erodible layer comprises a mixture of hydroxypropyl methylcellulose, polyvinyl alcohol, or polyvinyl alcohol-polyethylene glycol graft copolymer and carboxymethyl cellulose or carboxymethyl cellulose sodium salt. 11. The pharmaceutical composition according to Claim 10, wherein the erodile layer further comprises microcrystalline cellulose.

12. The pharmaceutical composition according to Claim 1, wherein the erodible layer partially or completely encapsulates the core.

~~13. The pharmaceutical composition according to Claim 1, further comprising an outer coating.~~

14. The pharmaceutical composition according to Claim 13, wherein the outer coating contains phenylephrine or a pharmaceutically acceptable salt.

15. The pharmaceutical composition according to Claim 13, wherein the outer coating is an outer coating.

16. The pharmaceutical composition according to Claim 13, wherein the outer coating comprises phenylephrine or a pharmaceutically acceptable salt thereof and polyvinyl alcohol.

17. The pharmaceutical composition according to Claim 13, wherein the outer coating comprises phenylephrine or a pharmaceutically acceptable salt thereof and polyvinyl alcohol-polyethylene glycol graft copolymer.

18. The pharmaceutical composition according to Claim 13, wherein the outer coating comprises 1-2% (w/w) phenylephrine or a pharmaceutically acceptable salt thereof; 6-10% (w/w) polyvinyl alcohol based polymer; and optionally 0.9-1% (w/w) loratadine.

19. The composition according to Claim 1, further comprising one or more additional therapeutic agent(s).

20. The composition according to Claim 4, further comprising one or more additional therapeutic agent(s).

21. The composition according to Claim 13, further comprising one or more additional therapeutic agent(s).

22. The composition according to Claim 21, wherein one or more additional therapeutic agent(s) is formulated in the core, the erodible layer, an outer coating, or any combination of two or more thereof.

23. The composition according to any one of Claims 1 or 4, further comprising one or more additional therapeutic agent(s).

24. The composition according to Claim 23 wherein one or more additional therapeutic agent(s) is selected from one or more of the group consisting of an antihistamine, an analgesic, an anti-pyretic and a non-steroidal anti-inflammatory agent.

25. The composition according to Claim 23 wherein one or more additional therapeutic agent(s) is formulated in immediate release form.

26. The composition according to Claim 23 wherein one or more additional therapeutic agent(s) is loratadine or desloratadine in immediate release form.

27. The composition according to Claim 19, wherein one or more additional therapeutic agent(s) is formulated in the erodible layer.

28. The composition according to Claim 20, wherein one or more additional therapeutic agent(s) is formulated in the erodible layer.

29 The composition according to Claim 21, wherein one or more additional therapeutic agent(s) is formulated in the erodible layer.

30 The composition according to Claim 22, wherein one or more additional therapeutic agent(s) is formulated in the erodible layer.

31 The composition according to Claim 23 wherein the composition is formulated as a capsule or a tablet.

32 The composition according to Claim 23 wherein one or more additional therapeutic agent(s) is in sustained release form.

33 The pharmaceutical composition of Claim 1, wherein the core further comprises one or more of the following components: hydroxypropyl cellulose, carboxymethylcellulose sodium, microcrystalline cellulose, and magnesium stearate.

34 The pharmaceutical composition of Claim 33, wherein the erodible layer further comprises one or more polyvinyl alcohol based polymer(s).

35 The pharmaceutical composition of Claim 34, wherein the erodible layer further comprises loratadine or desloratadine.

36 The pharmaceutical composition of Claim 1, wherein

- the core comprises the following components: about 4-5% (w/w) phenylephrine or a pharmaceutically acceptable salt thereof, about 4-5% (w/w) hydroxypropyl cellulose 300-600 cPs at 10%, about 4-5% (w/w) hydroxypropyl cellulose 150 – 300 cPs at 2%, about 16-17% (w/w) carboxymethylcellulose sodium salt, about 59-61% (w/w) microcrystalline cellulose, and about 0.9-1% (w/w) magnesium stearate; and
- the erodible layer comprises the following components: about 1-2% (w/w) phenylephrine or a pharmaceutically acceptable salt thereof, and about 6-10% (w/w) polyvinyl alcohol based polymer.

37 The pharmaceutical composition of Claim 36, wherein the polyvinyl alcohol based polymer is a polyvinyl alcohol-polyethylene glycol graft copolymer.

38 The pharmaceutical composition of Claim 36, wherein the erodible layer further comprises about 0.9-1% (w/w) loratadine or desloratadine.

39 The pharmaceutical composition of Claim 1, wherein the core comprises the following components: about 22.5 mg phenylephrine or a pharmaceutically acceptable salt thereof, about 25 mg hydroxypropyl cellulose 300-600 cPs at 10%, about 25 mg hydroxypropyl cellulose 150 – 300 cPs at 2%, about 90 mg carboxymethylcellulose sodium salt, about 332.5 mg microcrystalline cellulose, and about 5 mg magnesium stearate.

40 The pharmaceutical composition of Claims 1, wherein the erodible layer comprises the following components: about 7.5 mg phenylephrine or a pharmaceutically acceptable salt thereof, and about 36-54 mg polyvinyl alcohol based polymer.

41 The pharmaceutical composition of Claim 40, wherein the polyvinyl alcohol based polymer is a polyvinyl alcohol-polyethylene glycol graft copolymer.

42 The pharmaceutical composition of Claim 40, wherein the erodible layer further comprises about 5 mg loratadine or desloratadine.

43. Use of a composition according to Claim 1, for the manufacture of a medicament for treating the symptoms of cold, influenza, allergy, or non-allergic rhinitis in a subject in need thereof.

44. The use according to Claim 43, wherein the composition is suitable for administration every 8 hours, 12 hours, or 24 hours.

45 A pharmaceutical composition suitable for oral administration. wherein the composition comprises a core comprising a polymer matrix comprising hydroxypropyl cellulose and carboxymethylcellulose sodium and phenylephrine or a pharmaceutically acceptable salt thereof. wherein the matrix completely erodes within about 4-12 hours after ingestion.

46. The pharmaceutical composition of claim 45, wherein the matrix completely erodes within about 4-8 hours after ingestion.

47. The pharmaceutical composition of claim 45, wherein a total amount of phenylephrine or pharmaceutically acceptable salt thereof is 30 mg.

48 The pharmaceutical composition of claim 45, wherein a total amount of phenylephrine or pharmaceutically acceptable salt thereof is 60 mg.

49 The composition according to claim 45, further comprising one or more additional therapeutic agent(s).

50. A pharmaceutical composition comprising phenylephrine or pharmaceutically acceptable salt thereof in an extended release core further comprising hydroxypropyl cellulose and carboxymethylcellulose sodium. and wherein a percent of unconjugated phenylephrine AUC_{0-24} relative to total phenylephrine AUC_{0-24} in the plasma of a subject after ingestion of the composition is at least about 1 to about 14%.

51. The pharmaceutical composition of claim 50, which comprises 30 mg of phenylephrine or pharmaceutically acceptable salt thereof.

52. The pharmaceutical composition of claim 50, which comprises 60 mg of phenylephrine or pharmaceutically acceptable salt thereof.

53. The composition according to claim 50, wherein the phenylephrine dissolution profile of the composition comprises a zero-order release phase.

Claims

1. A pharmaceutical composition suitable for oral administration, wherein the composition comprises:

a) a core comprising a polymer matrix comprising hydroxypropylcellulose and carboxymethylcellulose sodium salt, and phenylephrine or a pharmaceutically acceptable salt thereof; and

b) an erodible layer, optionally comprising phenylephrine or a pharmaceutically acceptable salt thereof;

wherein upon ingestion of the composition by a subject at least a portion of phenylephrine is absorbed in the colon of the subject.

2. The pharmaceutical composition of Claim 1, wherein at least 5% by weight of phenylephrine or a pharmaceutically acceptable salt thereof is absorbed in the colon of the subject.

3. The pharmaceutical composition according to Claim 1, wherein the core comprises one or more pellets comprising phenylephrine or a pharmaceutically acceptable salt thereof.

4. The pharmaceutical composition according to Claim 3, wherein one or more pellets have an erodible pellet coating on the surface of said pellet(s).

5. The pharmaceutical composition according to Claim 4, wherein the erodible pellet coating comprises a pH-sensitive polymer or a colon-specific polymer.

6. The pharmaceutical composition according to Claim 1, wherein the core further comprises a penetration enhancer.

7. The pharmaceutical composition according to Claim 1, wherein the erodible layer comprises a mixture of hydroxypropyl methylcellulose, polyvinyl alcohol, or polyvinyl alcohol-polyethylene glycol graft copolymer and carboxymethyl cellulose or carboxymethyl cellulose sodium salt.

8. The pharmaceutical composition according to Claim 7, wherein the erodile layer further comprises microcrystalline cellulose.

9. The pharmaceutical composition according to Claim 1, wherein the erodible layer partially or completely encapsulates the core.

10. The pharmaceutical composition of Claim 1, wherein the core further comprises microcrystalline cellulose and/or magnesium stearate.

11. The pharmaceutical composition of Claim 10, wherein the erodible layer comprises one or more polyvinyl alcohol based polymer(s).

12. The pharmaceutical composition of Claim 11, wherein the erodible layer further comprises loratadine or desloratadine.

13. The pharmaceutical composition of Claim 1,

wherein the core comprises the following components:

about 4-5% (w/w) phenylephrine or a pharmaceutically acceptable salt thereof,

about 4-5% (w/w) hydroxypropyl cellulose 300-600 cPs at 10%,

about 4-5% (w/w) hydroxypropyl cellulose 150-300 cPs at 2%,

about 16-17% (w/w) carboxymethylcellulose sodium salt,

about 59-61% (w/w) microcrystalline cellulose, and

about 0.9-1% (w/w) magnesium stearate; and

the erodible layer comprises the following components:

about 1-2% (w/w) phenylephrine or a pharmaceutically acceptable salt thereof, and

about 6-10% (w/w) polyvinyl alcohol based polymer;

in each case based on the total weight of the pharmaceutical composition.

14. The pharmaceutical composition of Claim 13, wherein the polyvinyl alcohol based polymer is a polyvinyl alcohol-polyethylene glycol graft copolymer.

15. The pharmaceutical composition of Claim 13, wherein the erodible layer further comprises about 0.9-1% (w/w) loratadine or desloratadine based on the total weight of the pharmaceutical composition.

16. The pharmaceutical composition of Claim 1, wherein the core comprises the following components:

about 22.5 mg phenylephrine or a pharmaceutically acceptable salt thereof,

about 25 mg hydroxypropyl cellulose 300-600 cPs at 10%,

about 25 mg hydroxypropyl cellulose 150-300 cPs at 2%,

about 90 mg carboxymethylcellulose sodium salt,

about 332.5 mg microcrystalline cellulose, and

about 5 mg magnesium stearate.

17. The pharmaceutical composition of Claim 1 or 16, wherein the erodible layer comprises the following components:

about 7.5 mg phenylephrine or a pharmaceutically acceptable salt thereof, and

about 36-54 mg polyvinyl alcohol based polymer.

18. The pharmaceutical composition of Claim 17, wherein the polyvinyl alcohol based polymer is a polyvinyl alcohol-polyethylene glycol graft copolymer.

19. The pharmaceutical composition of Claim 17, wherein the erodible layer further comprises about 5 mg loratadine or desloratadine.

20. The pharmaceutical composition according to Claim 1, further comprising an outer coating.

21. The pharmaceutical composition according to Claim 20, wherein the outer coating contains phenylephrine or a pharmaceutically acceptable salt thereof.

22. The pharmaceutical composition according to Claim 20, wherein the outer coating is an enteric coating.

23. The pharmaceutical composition according to Claim 20, wherein the outer coating comprises phenylephrine or a pharmaceutically acceptable salt thereof and polyvinyl alcohol.

24. The pharmaceutical composition according to Claim 20, wherein the outer coating comprises phenylephrine or a pharmaceutically acceptable salt thereof and polyvinyl alcohol-polyethylene glycol graft copolymer.

25. The pharmaceutical composition according to Claim 20, wherein the outer coating comprises:

1-2% (w/w) phenylephrine or a pharmaceutically acceptable salt thereof,

6-10% (w/w) polyvinyl alcohol based polymer, and

optionally 0.9-1% (w/w) loratadine;

in each case based on the total weight of the pharmaceutical composition.

26. The pharmaceutical composition according to claim 1, wherein the erodible layer is a colon-specific layer;

wherein upon ingestion by a subject the colon-specific layer degrades by an action of a colon-specific condition in the subject.

27. The pharmaceutical composition according to Claim 26, wherein the colon-specific condition is a colon-specific enzyme.

28. The pharmaceutical composition according to Claim 27, wherein the colon-specific layer comprises one or more polymers selected from one or more of the group consisting of: N,N-dimethylacrylamide, N-t-butylacrylamide, acrylic acid cross-linked with azoaromatic compounds, chitosan, shellac, pea starch, amylose, amylose ethylcellulose, and a combination of pectin, chitosan and hydroxylpropyl methylcellulose.

29. The pharmaceutical composition according to Claim 26, wherein the colon-specific layer encapsulates the core.

30. The pharmaceutical composition according to Claim 26, further comprising a further erodible layer optionally comprising phenylephrine or a pharmaceutically acceptable salt thereof.

31. The pharmaceutical composition according to Claim 26 or 30, further comprising an outer coating.

32. The pharmaceutical composition according to Claim 31, wherein the outer coating is an enteric coating.

33. The pharmaceutical composition according to Claim 30, wherein the erodible layer encapsulates the colon-specific layer.

34. The pharmaceutical composition for oral administration according to claim 1, wherein the erodible layer is a pH-sensitive layer which completely disintegrates under a pH condition in the colon.

35. The pharmaceutical composition according to Claim 34, wherein the pH condition is from about pH 5.5 to about pH 7.0.

36. The pharmaceutical composition according to Claim 35, wherein the pH condition is from about pH 5.7 to about pH 6.8.

37. The pharmaceutical composition according to Claim 34, further comprising a further erodible layer encapsulating the pH-sensitive layer and the core, the further erodible layer optionally comprising phenylephrine or a pharmaceutically acceptable salt thereof.

38. The pharmaceutical composition according to Claim 34 or 35, further comprising an outer coating.

39. The pharmaceutical composition according to Claim 38, wherein the outer coating is an enteric coating.

40. The pharmaceutical composition according to Claim 34, wherein the pH-sensitive layer encapsulates the core.

41. The pharmaceutical composition according to Claim 1, 26, or 34, further comprising a top coating.

42. The pharmaceutical composition according to Claim 1, 3, 20, 26 or 34, further comprising one or more additional therapeutic agent(s).

43. The pharmaceutical composition according to Claim 22, wherein one or more additional therapeutic agent(s) is formulated in the core, the erodible layer, an outer coating, or any combination of two or more thereof.

44. The pharmaceutical composition according to Claim 1, 3, 20 or 43, wherein one or more additional therapeutic agent(s) is formulated in the erodible layer.

45. The pharmaceutical composition according to any one of Claims 42 to 44, wherein one or more additional therapeutic agent(s) is selected from one or more of the group consisting of an antihistamine, an analgesic, an anti-pyretic and a non-steroidal anti-inflammatory agent.

46. The pharmaceutical composition according to Claim 45, wherein the antihistamine is selected from the group consisting of diphenhydramine, chlorpheniramine, tripelennamine, promethazine, clemastine, doxylamine, astemizole, terfenadine, cimetidine, famotidine, nizatidine, ranitidine, cromolyn, loratadine, desloratadine, azatidine, fexofenadine, terfenadine, cetirizine, astemizole, and levocabastine, pharmaceutically acceptable salts thereof and combinations thereof.

47. The pharmaceutical composition according to any one of Claims 42 to 44, wherein one or more additional therapeutic agent(s) is formulated in immediate release form.

48. The pharmaceutical composition according to any one of Claims 42 to 44, wherein one or more additional therapeutic agent(s) is loratadine or desloratadine in immediate release form.

49. The pharmaceutical composition according to any one of Claims 42 to 44, wherein the composition is formulated as a capsule or a tablet.

50. The pharmaceutical composition according to any one of Claims 42 to 44, wherein one or more additional therapeutic agent(s) is in sustained release form.

51. The pharmaceutical composition according to any one of Claims 1 to 50 for use as a medicament for treating the symptoms of cold, influenza, allergy, or non-allergic rhinitis.

52. The pharmaceutical composition according to Claim 51, wherein the medicament is in a form for administration every 8 hours, 12 hours, or 24 hours.