Claims

1. A pharmaceutical flotation device suitable for extended release of a pharmaceutical product in a stomach of a subject, the flotation device comprising a polymeric matrix that comprises:

a first polymeric material;

a second polymeric material; and

a crosslinking agent, wherein:

the first polymeric material and the second polymeric material form a hydrogel network; and the crosslinking agent is configured to generate additional crosslinks in at least the first polymeric material upon exposure to an aqueous solution having a pH of from 1 to 5.

2. The pharmaceutical flotation device according to Claim 1, wherein the pharmaceutical flotation device is provided in a first portion shaped as a hollow vessel and one or more second portions shaped as a cap and/or a plug, such that a pharmaceutical product can be deposited within the hollow vessel and sealed inside by the cap and/or plug.

3. The pharmaceutical flotation device according to Claim 1, wherein a pharmaceutical product is encapsulated within the polymeric matrix of the pharmaceutical flotation device.

4. The pharmaceutical flotation device according to any one of the preceding claims, wherein one or more of the following apply:

(i) the polymeric matrix further comprises an oil, optionally wherein the oil is selected from one or more of the group consisting of olive oil, fish oil, corn oil, sunflower seed oil, grape seed oil, canola oil, avocado oil, and coconut oil (e.g. the oil is coconut oil);

(ii) the first polymeric material is selected from one or more of the group consisting of a pectin, and an alginate;

(iii) the second polymeric material is selected from one or more of the group consisting of resistant starch, kappa-carrageenan, agarose, iota-carrageenan, cellulose, methylcellulose, ethyl cellulose, and gelatine, optionally wherein the second polymeric material is kappa-carrageenan; and

(iv) the crosslinking agent is a bivalent metal carbonate, optionally wherein the bivalent metal carbonate is $CaCO_3$.

5. The pharmaceutical flotation device according to any one of the preceding claims, wherein:

(a) the wt:wt ratio of the first polymeric material to the second polymeric material is from 1:10 to 10:1, such as about 1:1; and/or

(b) the wt:wt ratio of the crosslinking agent to the first polymeric material is from 1:10 to 10:1, such as about 1:1.

6. The pharmaceutical flotation device according to any one of the preceding claims, wherein the polymeric matrix comprises:

sodium alginate;

kappa-carageenan; and

$CaCO_3$, where

the wt:wt ratio of the sodium alginate : kappa-carageenan : $CaCO_3$ is about 1:1:1, optionally wherein the polymeric matrix further comprises coconut oil.

7. The pharmaceutical flotation device according to any one of Claims 2 and 4 to 6, as dependent upon Claim 2, wherein the pharmaceutical flotation device further comprises a pharmaceutical product.

8. The pharmaceutical flotation device according to any one of Claims 3, 4 to 6 as dependent upon Claim 3, and Claim 7, wherein the pharmaceutical product is in the form of: particles of one or more active pharmaceutical ingredients; particles of one or more active pharmaceutical ingredients and pharmaceutically acceptable excipients; a tableted formulation; a capsule formulation; drug-loaded microparticles; and drug-loaded fibre meshes.

9. The pharmaceutical flotation device according to any one of the preceding claims, wherein the hydrogel network is an interpenetrating network.

10. A method of forming a pharmaceutical flotation device according to any one of Claims 1 to 9, the method comprising the steps of:

(a) providing a solution mixture comprising:

a first polymeric material;

a second polymeric material;

a crosslinking agent; and

water, where the first polymeric material and the second polymeric material interact to form a hydrogel network;

(b) placing the solution mixture into a mould, solidifying the solution mixture and removing the water to provide a pharmaceutical flotation device.

11. The method according to Claim 10, wherein step (b) is conducted using at least two moulds, so as to form a first portion shaped as a hollow vessel and one or more second portions shaped as a cap and/or a plug, such that a pharmaceutical product can be deposited within the hollow vessel and sealed inside by the cap and/or plug.

12. The method according to Claim 10 or Claim 11, wherein the solution mixture further comprises a pharmaceutical product.

13. The method according to any one of Claims 10 to 12, wherein the solution mixture further comprises an oil, optionally wherein the oil is selected from one or more of the group consisting of olive oil, fish oil, corn oil, sunflower seed oil, grape seed oil, canola oil, avocado oil, and coconut oil (e.g. the oil is coconut oil).

14. The method according to any one of Claims 10 to 13, wherein one or more of the following apply:
(a) the first polymeric material is selected from one or more of the group consisting of a pectin, and an alginate;
(b) the second polymeric material is selected from one or more of the group consisting of resistant starch, kappa-carrageenan, agarose, iota-carrageenan, cellulose, methylcellulose, ethyl cellulose, and gelatine, optionally wherein the second polymeric material is kappa-carrageenan; and
(c) the solution mixture of step (a) is heated to a temperature of greater than 40 ºC for a first period of time and is then cooled to about 40 ºC for a second period of time before step (b) of the method is conducted, optionally wherein the mould in step (b) has been cooled to a temperature of less than 25 ºC.

15. The method according to any one of Claims 10 to 14, wherein the crosslinking agent is a bivalent metal carbonate, optionally wherein the bivalent metal carbonate is $CaCO_3$.

16. The method according to any one of Claims 10 to 15, wherein the wt:wt ratio of the first polymeric material to the second polymeric material is from 1:10 to 10:1, such as about 1:1, optionally wherein the maximum concentration of each of the first polymeric material and the second polymeric material in the solution mixture is from 1 to 2 wt%/volume, such as about 1.5 wt%/volume.

17. The method according to any one of Claims 10 to 16, wherein the wt:wt ratio of the crosslinking agent to the first polymeric material is from 1:10 to 10:1, such as about 1:1, optionally wherein the maximum concentration of crosslinking agent in the solution mixture is from 1 to 2 wt%/volume, such as about 1.5 wt%/volume.

18. The method according to any one of Claims 12 and 13 to 17, as dependent upon Claim 12, wherein the pharmaceutical product is in the form of: particles of one or more active pharmaceutical ingredients; particles of one or more active pharmaceutical ingredients and pharmaceutically acceptable excipients; a tableted formulation; a capsule formulation; drug-loaded microparticles; and drug-loaded fibre meshes.

19. The method according to any one of Claims 10 to 18, wherein the hydrogel network is an interpenetrating network.

20. A pharmaceutical formulation comprising a pharmaceutical flotation device according to any one of Claims 1 to 9 and a pharmaceutical product, optionally wherein the pharmaceutical product is in the form of: particles of one or more active pharmaceutical ingredients; particles of one of more active pharmaceutical ingredients and pharmaceutically acceptable excipients; a tableted formulation; a capsule formulation; drug-loaded microparticles; and drug-loaded fibre meshes.