CBD is highly lipophilic, sensitive to light and largely broken down in the duodenum contributing to extremely low oral bioavailability in plasma and tissues (approximately 6% and 1%, respectively). Whilst chronic usage of CBD is clinically well tolerated, its high volatility and instability poses limitations for use in research and adaptation as a pharmacotherapy. The high cost of using such a drug, which only has low oral bioavailability, may also be prohibitive for many in need.

There is a need for strategies that mitigate at least one of the problems outlined above, for example, being able to deliver a cannabinoid, or a mixture of cannabinoids, to the brain to treat a neurological condition, or to prolong the residence time of the cannabinoid in an organ such as the brain, or to enhance the uptake of the cannabinoid in an organ such as the brain, or to provide a cost-effective treatment for such conditions, or to protect the cannabinoid, or a mixture of cannabinoids, from light or air, or to reduce or eliminate the amount of degradation during storage or administration.

SUMMARY

The present disclosure is predicated at least in part on the discovery that a composition comprising an encapsulated cannabinoid or mixture of cannabinoids, along with a permeation enhancer, may be suitable for delivery to the brain to treat a neurological condition, or at least provide an alternative to the solutions presently available.

In an aspect, there is provided a composition comprising one or more cannabinoids; a permeation enhancer which is a bile acid; and an alginate polymer; wherein the one or more cannabinoids and permeation enhancer are encapsulated.

In another aspect, there is provided a process for preparing a cannabinoid composition, wherein the cannabinoid composition comprises: one or more cannabinoids; a permeation enhancer which is a bile acid; and an alginate polymer; the process comprising: mixing an aqueous solution of the one or more cannabinoids and the alginate polymer to form an emulsion, then casting the emulsion into an aqueous solution of a multivalent salt to form an encapsulated cannabinoid particle.

In another aspect, there is provided the use of a composition as defined above in the manufacture of a medicament to enhance brain permeation of one or more cannabinoids.

In another aspect, there is provided a composition as defined above for use in therapy.

In one example, the present disclosure provides a composition comprising one or more cannabinoids; a permeation enhancer; and an alginate polymer; wherein the one or more cannabinoids and permeation enhancer are encapsulated.

In another example, the present disclosure provides a process for preparing a cannabinoid composition, wherein the cannabinoid composition comprises:

one or more cannabinoids;

a permeation enhancer; and

an alginate polymer;

the process comprising:

mixing an aqueous solution of the one or more cannabinoids and the alginate polymer to form an emulsion, then casting the emulsion into an aqueous solution of a multivalent salt to form an encapsulated cannabinoid particle.

In some examples, the permeation enhancer is encapsulated together with the one or more cannabinoids. In other examples the one or more cannabinoids and permeation enhancer are encapsulated separately, the process further comprising the steps of encapsulating the permeation enhancer by mixing an aqueous solution of the permeation enhancer and the alginate polymer to form an emulsion, then casting the emulsion into an aqueous solution of a multivalent salt to form an encapsulated permeation enhancer particle, and combining the encapsulated cannabinoid particle and the encapsulated permeation enhancer particle to form the composition of the disclosure.

Other examples of the present disclosure will become apparent to those ordinarily skilled in the art upon review of the following description of specific examples of the disclosure.

BRIEF DESCRIPTION OF THE FIGURE

For a further understanding of the aspects and advantages of the present invention, reference should be made to the following detailed description, taken in conjunction with the accompanying drawing, in which:

Figure 1 shows mean concentration-time curve of a cannabinoid, cannabidiol (CBD), in plasma and brain (a, c) with corresponding cumulative concentrations shown as area under curve (AUC) graphs (b, d). CBD was administered orally to mice at a dosage of 5 mg/kg according to the following formulations: encapsulated CBD (Capsule); encapsulated CBD plus encapsulated deoxycholic acid (4 mg/kg) (Capsule+DCA) and CBD with oil (Naked). For each graph, the data represents mean ± SEM bars (n = 3 or 4 per treatment group for each timepoint). Analysis using one-way ANOVA revealed no statistical significance, with plasma and brain data yielding $p = 0.07$ and $p = 0.67$, respectively.

DETAILED DESCRIPTION OF THE INVENTION

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by those of ordinary skill in the art to which the invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, preferred methods and materials are described. For the purposes of the present invention, the following terms are defined below.

The articles "a" and "an" are used herein to refer to one or to more than one (i.e. to at least one) of the grammatical object of the article. By way of example, “an element” means one element or more than one element.

Claims:

1. A composition comprising:
one or more cannabinoids;
a permeation enhancer which is a bile acid; and
an alginate polymer;
wherein the one or more cannabinoids and permeation enhancer are encapsulated.

2. The composition according to claim 1, wherein the one or more cannabinoids and permeation enhancer are encapsulated separately.

3. The composition according to claim 1 or claim 2, wherein the composition has a t_{max} for brain penetration of the one or more cannabinoids of less than 1 hour.

4. The composition according to any one of claims 1 to 3, wherein the one or more cannabinoids are selected from the group consisting of THC, THCV, CBD, CBN, CBG, CBC, and CBND, or any combination thereof.

5. The composition according to any one of claims 1 to 4, wherein bile acid is deoxycholic acid.

6. The composition according to any one of claims 1 to 5, wherein the alginate polymer is sodium alginate.

7. The composition according to any one of claims 1 to 6, wherein the molar ratio of the one or more cannabinoids to permeation enhancer is from about 20:1 to about 1:20.

8. A process for preparing a cannabinoid composition, wherein the cannabinoid composition comprises:
one or more cannabinoids;
a permeation enhancer which is a bile acid; and
an alginate polymer;
the process comprising:
mixing an aqueous solution of the one or more cannabinoids and the alginate polymer to form an emulsion, then casting the emulsion into an aqueous solution of a multivalent salt to form an encapsulated cannabinoid particle.

9. The process according to claim 8, wherein the one or more cannabinoids and bile acid are encapsulated together.

10. The process according to claim 8, wherein the one or more cannabinoids and bile acid are encapsulated separately.

11. The process according to claim 10, further comprising the steps of:

i) mixing an aqueous solution of the bile acid and the alginate polymer to form an emulsion, then casting the emulsion into an aqueous solution of a multivalent salt to form an encapsulated bile acid particle; and

ii) mixing the encapsulated bile acid particle with the encapsulated cannabinoid particle.

12. The process according to any one of claims 8 to 11, wherein the one or more cannabinoids are provided as a solution dissolved in medium chain triglyceride.

13. The process according to any one of claims 8 to 12, wherein the one or more cannabinoids are selected from the group consisting of THC, THCV, CBD, CBN, CBG, CBC, and CBND, or any combination thereof.

14. The process according to any one of claims 8 to 13, wherein the bile acid is deoxycholic acid.

15. The process according to any one of claims 8 to 14, wherein the alginate polymer is medium viscosity sodium alginate.

16. The process according to any one of claims 8 to 15, wherein the multivalent salt is calcium chloride.

17. The process according to any one of claims 8 to 16, wherein the molar ratio of the one or more cannabinoids to permeation enhancer is from about 20:1 to about 1:20.

18. Use of a composition according to any one of claims 1 to 7 in the manufacture of a medicament to enhance brain permeation of one or more cannabinoids.

19. A composition according to any one of claims 1 to 7 for use in therapy.