Sleep Disorder Compositions and Treatments Thereof

Field

[0001] The invention relates to a method for treating a sleep disorder. The invention also relates to a pharmaceutical composition comprising an extract from a *Cannabis* plant, and its use in the treatment of the sleep disorder.

Background

[0002] The biological activity of *Cannabis* is well known, and has led it to become a "recreational" drug. However, with the discovery of a class of cannabinoid (CB) receptors, and the relaxation of laws regulating *Cannabis* use - in some jurisdictions decriminalisation - there now exists the opportunity to explore the potential of *Cannabis* as a source of new therapeutics.

[0003] There is also a growing movement of patients suffering from chronic diseases, such as sleep disorders, to seek natural remedies as alternative or complementary therapy.

[0004] Accordingly, there is a continuing need to develop new treatments for sleep disorders, which are derived, at least in part, from a natural source.

Summary

[0005] The invention provides a method of treating a sleep disorder comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition comprising a *Cannabis* extract. Accordingly, also provided is a pharmaceutical composition comprising the *Cannabis* extract and optionally one or more pharmaceutically acceptable carriers, diluents, adjuvants, excipients or any combination thereof.

[0006] The *Cannabis* extract comprises a cannabinoid fraction and a terpene fraction. The cannabinoid fraction typically comprises as the primary cannabinoid Δ^9-Tetrahydrocannabinol (THC). The cannabinoid fraction may also comprise one or more further cannabinoids including Cannabidiol (CBD) and Cannabinol (CBN). The terpene fraction typically comprises beta-myrcene, linalool and nerolidol. Preferably the *Cannabis* extract does not contain (or contains very low levels, such as not more than about 0.001wt%) Δ^9-Tetrahydrocannabivarin (THCV), alpha-pinene or beta-pinene, terpinolene, caryophyllene, humulene and limonene.

[0006a] In one aspect, the present disclosure refers to a pharmaceutical composition comprising a *Cannabis* extract and optionally one or more pharmaceutically acceptable carriers,

diluents, adjuvants, excipients or any combination thereof, the *Cannabis* extract comprising a cannabinoid fraction comprising Δ^9-Tetrahydrocannabinol (THC), Cannabidiol (CBD), and Cannabinol (CBN) and a terpene fraction in an amount of at least 3% by weight of the extract.

[0006b] In another aspect, the present disclosure refers to a medicament comprising an effective amount of the pharmaceutical composition as disclosed herein.

[0006c] In another aspect, the present disclosure refers to a use of an effective amount of the pharmaceutical composition as disclosed herein in the manufacture of a medicament for treating a sleep disorder.

[0006d] In yet another aspect, the present disclosure refers to a use of a *Cannabis* extract in the preparation of a medicament for treating a sleep disorder, wherein the *Cannabis* extract comprises a cannabinoid fraction comprising Δ^9-Tetrahydrocannabinol (THC), Cannabidiol (CBD) and Cannabinol (CBN) and a terpene fraction in an amount of at least 3% by weight of the extract.

[0007] In a further example, there is provided use of the *Cannabis* extract in the preparation of a medicament for treating a sleep disorder.

[0008] In yet another example, there is provided a pharmaceutical composition for treating a sleep disorder, wherein the pharmaceutical composition comprises a *Cannabis* extract and optionally one or more pharmaceutically acceptable carriers, diluents, adjuvants, excipients or any combination thereof.

Description of Embodiment(s)

[0009] The present invention provides a pharmaceutical composition comprising a *Cannabis* extract and optionally one or more pharmaceutically acceptable carriers, diluents, adjuvants, excipients or any combination thereof.

[0010] *Cannabis* plants produce a diverse array of secondary metabolites, including cannabinoids, terpenes and terpenoids, sterols, triglycerides, alkanes, squalenes, tocopherols, carotenoids and alkaloids. The mix of these secondary metabolites varies depending on several factors, including *Cannabis* variety, part of the *Cannabis* plant extracted, method of extraction, processing of the extract, and season.

[0011] There are several varieties of *Cannabis* plant, which have been described under two distinct naming conventions. One of these conventions identifies three distinct species of *Cannabis* plant, namely *Cannabis sativa Linnaeus, Cannabis indica* LAM., and *Cannabis ruderalis.* Another convention identifies all *Cannabis* plants as belonging to the *Cannabis sativa* L. species, with the various varieties divided amongst several subspecies, including: *Cannabis sativa* ssp. *sativa* and ssp. *indica.* As used herein, the term "*Cannabis*" refers to any and all of these plant varieties.

[0012] The extracts may be formed from any part of the *Cannabis* plant containing cannabinoid, terpene and terpenoid compounds. Extracts may be formed by contacting an extractant with a leaf, seed, trichome, flower, keif, shake, bud, stem or a combination thereof. In some embodiments, the extract is formed from the flowers and shake of a *Cannabis* plant. Suitable extractants include, for example, alcohols (e.g., methanol, ethanol, propanol, butanol, propylene glycol, etc.), water, hydrocarbons (e.g., butane, hexane, etc.), oils (e.g., olive oil, vegetable oil, essential oil, etc.), a solvent (e.g., ethyl acetate, polyethylene glycol, etc.) or a supercritical fluid (e.g., liquid CO_2).

[0013] The extractant may be completely or partially removed prior to incorporation of the *Cannabis* extract into the pharmaceutical composition, or it may be included in the pharmaceutical composition as a carrier. The extractant may be removed by heating the extract

Claims

1. A pharmaceutical composition comprising a *Cannabis* extract and optionally one or more pharmaceutically acceptable carriers, diluents, adjuvants, excipients or any combination thereof, the *Cannabis* extract comprising a cannabinoid fraction comprising Δ^9-Tetrahydrocannabinol (THC), Cannabidiol (CBD), and Cannabinol (CBN) and a terpene fraction in an amount of at least 3% by weight of the extract.

2. The pharmaceutical composition of claim 1, comprising THC in an amount from 5% to 90% by weight of the extract.

3. The pharmaceutical composition of claim 1 or 2, comprising CBD in an amount from 1% to 20% by weight of the extract.

4. The pharmaceutical composition of any one of claims 1 to 3, comprising CBN in an amount from 1% to 20% by weight of the extract.

5. The pharmaceutical composition of any one of claims 1 to 4, wherein the terpene fraction comprises one or more of linalool, myrcene, and nerolidol.

6. The pharmaceutical composition of any one of claims 1 to 5, wherein the terpene fraction comprises beta-myrcene in an amount from 1% to 50% by weight of the terpene fraction.

7. The pharmaceutical composition of any one of claims 1 to 6, wherein the THC is a main cannabinoid.

8. The pharmaceutical composition of any one of claims 1 to 7, wherein the ratio of THC:CBN is from 5:1 to 20:1.

9. The pharmaceutical composition of any one of claims 1 to 8, wherein the ratio of THC:CBD is from 10:1 to 50:1.

10. The pharmaceutical composition of any one of claims 1 to 9, wherein the *Cannabis* extract is a *Cannabis* oil.

11. The pharmaceutical composition of any one of claims 1 to 10, the *Cannabis* extract comprises the terpene fraction in an amount of less than 50% by weight of the extract.

12. The pharmaceutical composition of any one of claims 1 to 11, wherein the ratio of the cannabinoid fraction:terpene fraction is about 8:1 to about 33:1.

13. The pharmaceutical composition of any one of claims 1 to 11, for treating a sleep disorder.

14. A medicament comprising an effective amount of the pharmaceutical composition of any one of claims 1 to 12.

15. Use of an effective amount of the pharmaceutical composition of any one of claims 1 to 12 in the manufacture of a medicament for treating a sleep disorder.

16. Use of a *Cannabis* extract in the preparation of a medicament for treating a sleep disorder, wherein the *Cannabis* extract comprises a cannabinoid fraction comprising Δ^9-Tetrahydrocannabinol (THC), Cannabidiol (CBD) and Cannabinol (CBN) and a terpene fraction in an amount of at least 3% by weight of the extract.