and unfreeze the capsules. This, however, can lead to a lack of treatment compliance, leading to patient unadherence.

Several attempts have been performed in order to reduce the aqueous component of the stool. Dewatering of the microbial community through techniques such as lyophilisation is one of the main routes. However, the dewatering process is physically demanding and reduces the viability of the microbes significantly. In addition, sometimes the dewatering of the microbial community is not enough to achieve the appropriate stability, and special containers have to be developed with that aim. As an example, KR20080059605 discloses the packaging of lyophilized bacteria in a container with a particular design to reduce the environment humidity in contact with the capsule. This Korean patent document provides, among others, stability data with the lyophilized bacteria with (Example 6) or without (Example 5) excipients. Example 6 provides data with capsules comprising lyophilized bacteria together with microcrystalline cellulose and magnesium stearate. It is remarkably that the capsule without excipients was more stable within the particular container than when the capsules were formulated with the excipients.

In spite of the efforts made until now, there is still the need of stable home-based FMT based on live bacterial cells.

SUMMARY

In a first aspect, the present disclosure refers to a solid oral pharmaceutical composition comprising a pharmaceutically effective amount of non-lyophilized living microorganisms and one or more pharmaceutically acceptable water absorbing excipient(s), wherein the composition has a water content, determined according to European Pharmacopoeia 9.4, section 2.5.12., from 0.5 to 30% with respect the total weight of the composition and wherein the water absorbing excipient(s) are cellulose-based excipients, or a pharmaceutically acceptable salt thereof.

In another aspect, the present disclosure refers to a process for preparing an oral pharmaceutical composition disclosed herein, wherein the process comprises mixing non-lyophilized living microorganisms with one or more water absorbing excipient(s) wherein the water absorbing excipient(s) are cellulose-based excipients, or a pharmaceutically acceptable salt thereof.

In yet another aspect, the present disclosure refers to a solid oral pharmaceutical composition disclosed herein, for use in therapy.

In a further aspect, the present disclosure refers to a use of a water absorbing excipient for stabilizing non-lyophilized living microorganisms in a pharmaceutical composition wherein the water absorbing excipient(s) are cellulose-based excipients, or a pharmaceutically acceptable salt thereof.

Claims

1. A solid oral pharmaceutical composition comprising a pharmaceutically effective amount of non-lyophilized living microorganisms and one or more pharmaceutically acceptable water absorbing excipient(s), wherein the composition has a water content, determined according to European Pharmacopoeia 9.4, section 2.5.12., from 0.5 to 30% with respect the total weight of the composition and wherein the water absorbing excipient(s) are cellulose-based excipients, or a pharmaceutically acceptable salt thereof.

2. The composition according to claim 1, which is a single capsule.

3. The composition according to any one of the preceding claims 1-2, wherein the living microorganism is fecal microbiota.

~~4. The composition according to any one of the preceding claims 1-3, wherein the water absorbing excipient is selected from: a cellulose-based excipient or a pharmaceutically acceptable salt thereof; kaolinite; talc; palygorskite; sepiolite; and smectites.~~

4~~5~~. The composition according to any one of the preceding claims 1-3~~4~~, wherein the water absorbing excipient is a cellulose ether derivative, a cellulose ester derivative, or a combination thereof.

5~~6~~. The composition according to any one of the preceding claims 1-4~~5~~, wherein the water absorbing excipient is microcrystalline cellulose (MCC).

6~~7~~. The composition according to any one of the preceding claims 1-5~~6~~, wherein the water content is comprised from 5 to 30% with respect to the total weight of the composition.

7~~8~~. The composition according to any one of the preceding claims 1-6~~7~~, wherein the composition comprises one or more additional pharmaceutically acceptable excipients.

8~~9~~. The composition according to claim 1-7~~8~~, wherein the composition comprises:

- a cryoprotectant; or, alternatively,
- a lubricant; or, alternatively,
- a cryoprotectant and a lubricant.

9~~10~~. The composition according to any of the preceding claims 1-8~~9~~, which comprises:

- fecal microbiota, a cellulose ether derivative, a stearate salt, and a cryoprotectant; or, alternatively,

- fecal microbiota, a cellulose ether derivative, a stearate salt, and glycerol; or, alternatively,
- fecal microbiota, a cellulose ether derivative, magnesium stearate, and glycerol; or, alternatively,
- fecal microbiota, MCC, a stearate salt, and glycerol; or, alternatively,
- fecal microbiota, MCC, magnesium stearate, and glycerol.

10~~11~~. A process for preparing an oral pharmaceutical composition according to any of the preceding claims, wherein the process comprises mixing non-lyophilized living microorganisms with one or more water absorbing excipient(s) wherein the water absorbing excipient(s) are cellulose-based excipients, or a pharmaceutically acceptable salt thereof.

11~~12~~. The process according to claim 10~~11~~, wherein the process comprises mixing an excess by weight of the water absorbing excipient(s) with respect to an amount of living microorganism expressed in volume units.

12~~13~~. The process according to any one of the claims 11-12, which further comprises adding a lubricant, being the weight ratio of water absorbing agent(s):lubricant comprised from 30:1 to 70:1.

13~~14~~. The solid oral pharmaceutical composition according to any one of the claims 1-9~~10~~, for use in therapy.

14~~15~~. Use of a water absorbing excipient for stabilizing non-lyophilized living microorganisms in a pharmaceutical composition wherein the water absorbing excipient(s) are cellulose-based excipients, or a pharmaceutically acceptable salt thereof.