However, there is still a commercial need for pharmaceutical formulations in which a variety of active agents can be made stable in a liquid environment, and stored for extended periods of time. In particular, prior art formulations do not provide a simple means by which to deliver active agents in particulate form having a reduced stability in the presence of aqueous media. Furthermore, the prior art does not provide a composition which can also be used to deliver active agents which are unpalatable or elicit an uncomfortable sensation in the mouth and/or throat (e.g. burning sensation) when swallowed. These factors are particularly important for liquid compositions intended for administration to children.

Accordingly, the present disclosure provides a pourable pharmaceutical composition suitable for oral administration, wherein the composition comprises at least one pharmaceutically active agent in particulate form, dispersed within a liquid phase which comprises one or more oils selected from mono-, di-, or triglycerides having one or more short-, medium-, or long-chain fatty acid residues, and refined natural lipid oils, and up to 15% w/w water, based on the overall composition.

In one aspect of the present disclosure, there is provided a pourable pharmaceutical composition suitable for oral administration, wherein the composition comprises at least one pharmaceutically active agent in micronised form, dispersed within a liquid phase which comprises at least one triglyceride of one or more medium-chain fatty acid residues, an anti-caking agent, and up to 15% w/w water, based on the overall composition.

In another aspect of the present disclosure, there is provided a pharmaceutical composition disclosed herein, for use in therapy.

In a further aspect of the present disclosure, there is provided a process for preparing a pharmaceutical composition disclosed herein, the process comprising providing a liquid phase which comprises at least one triglyceride of one or more medium-chain fatty acid residues, an anti-caking agent, and up to 15% w/w water, based on the overall composition, and homogeneously dispersing the at least one pharmaceutically active agent in micronised form in the liquid phase.

Surprisingly, it has been found that compositions of this type can be used to formulate active agents which are otherwise unstable in liquid environments, especially in the presence of water. The compositions exhibit excellent storage stability in accordance with ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) guidelines. In addition, the compositions are appropriate for active agents which are poorly soluble or entirely insoluble in water.

The terms "active agent," "drug" and "pharmaceutically active agent" as used herein refer to a chemical material or compound which, when administered to an organism (human or animal, preferably human), induces a desired pharmacological effect. Included in the meaning of these terms are derivatives of the pharmaceutically active agent such as pharmaceutically acceptable salts.

The terminology "% w/w" as used herein refers to the relative amount of a component in terms of weight, based on the overall composition.

Claims

1. A pourable pharmaceutical composition suitable for oral administration, wherein the composition comprises at least one pharmaceutically active agent in micronised form, dispersed within a liquid phase which comprises at least one triglyceride of one or more medium-chain fatty acid residues, an anti-caking agent, and up to 15% w/w water, based on the overall composition.
2. The pharmaceutical composition according to claim 1, wherein the liquid phase comprises up to 2% w/w water, based on the overall composition.
3. The pharmaceutical composition according to claim 1 or claim 2, wherein the liquid phase comprises essentially no water.
4. The pharmaceutical composition according to any one of claims 1 to 3, wherein the liquid phase is present as a single phase.
5. The pharmaceutical composition according to any preceding claim, wherein the at least one pharmaceutically active agent is present in a concentration of 0.001% w/w to 5% w/w, based on the overall composition.
6. The pharmaceutical composition according to claim 5, wherein the at least one pharmaceutically active agent is present in a concentration of 0.1% w/w to 1% w/w, based on the overall composition.
7. The pharmaceutical composition according to any preceding claim, wherein the liquid phase further comprises one or more hydrophilic liquid components selected from glycerine, α-propylene glycol, β-propylene glycol, and polyethylene glycol.
8. The pharmaceutical composition according to any preceding claim, wherein the at least one triglyceride of one or more medium-chain fatty acid residues is present in a concentration range of 1% w/w to 99% w/w, based on the overall composition.
9. The pharmaceutical composition according to claim 8, wherein the at least one triglyceride of one or more medium-chain fatty acid residues is present in a concentration range of 10% w/w to 99% w/w, based on the overall composition.

10. The pharmaceutical composition according to any one of claims 7 to 9, wherein the hydrophilic liquid component is present in a concentration range of 10% w/w to 99% w/w, based on the overall composition.

11. The pharmaceutical composition according to any preceding claim, wherein the at least one pharmaceutically active agent has a particle size diameter in the range of 2 nm to 1 μm.

12. The pharmaceutical composition according to claim 11, wherein the at least one pharmaceutically active agent has a particle size diameter in the range of 100 nm to 0.5 μm.

13. The pharmaceutical composition according to any preceding claim, wherein the at least one pharmaceutically active agent is bendroflumethiazide, or a pharmaceutically acceptable salt thereof.

14. The pharmaceutical composition according to any preceding claim, wherein the at least one pharmaceutically active agent is amlodipine, or a pharmaceutically acceptable salt thereof.

15. The pharmaceutical composition according to any preceding claim, wherein the anti-caking agent is colloidal silicon dioxide.

16. A pharmaceutical composition according to any preceding claim, for use in therapy.

17. A process for preparing a pharmaceutical composition according to any one of claims 1 to 15, the process comprising providing a liquid phase which comprises at least one triglyceride of one or more medium-chain fatty acid residues, an anti-caking agent, and up to

15% w/w water, based on the overall composition, and homogeneously dispersing the at least one pharmaceutically active agent in micronised form in the liquid phase.