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, wherein the at least one micronised pharmaceutically active agent is bendroflumethiazide or amlodipine, or a pharmaceutically acceptable salt thereof, and wherein the liquid phase comprises up to 2% 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, wherein the at least one micronised pharmaceutically active agent is bendroflumethiazide or amlodipine, or a pharmaceutically acceptable salt thereof, and wherein the liquid phase comprises up to 2% w/w water, 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, wherein the at least one micronised pharmaceutically active agent is bendroflumethiazide or amlodipine, or a pharmaceutically acceptable salt thereof, and wherein the liquid phase comprises up to 2% w/w water, based on the overall composition.
2. The pharmaceutical composition according to claim 1, wherein the liquid phase comprises essentially no water.
3. The pharmaceutical composition according to claim 1 or claim 2, wherein the liquid phase is present as a single phase.
4. 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.
5. The pharmaceutical composition according to claim 4, 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.
6. 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.
7. 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.
8. The pharmaceutical composition according to claim 7, 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.
9. The pharmaceutical composition according to claim 6, wherein the hydrophilic liquid component 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 preceding claim, wherein the at least one pharmaceutically active agent has a particle size diameter in the range of 2 nm to 1 μm.

11. The pharmaceutical composition according to claim 10, wherein the at least one pharmaceutically active agent has a particle size diameter in the range of 100 nm to 0.5 μm.

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

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

14. A process for preparing a pharmaceutical composition according to any one of claims 1 to 12, 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, wherein the at least one micronised pharmaceutically active agent is bendroflumethiazide or amlodipine, or a pharmaceutically acceptable salt thereof, and wherein the liquid phase comprises up to 2% w/w water, based on the overall composition.