suspension or solution can be sprayed onto the surface of the API particles to form a coating film by evaporation of the solvent or water. Examples of technologies for wet particle coating include microencapsulation, fluid bed coating, solvent evaporation, spray drying, pan coating etc. In dry particle coating (also referred to as solventless coating), API particles are mechanically coated with fine particles of inactive ingredients (polymers and additives) to form particle composites. Examples of dry particle coating include hot melt coating, supercritical coating, impaction coating, electrostatic coating, etc. APIs particles coated with a taste-masking inactive ingredient may provide a more pleasant experience for a patient having difficulties swallowing or having a sensitivity to taste that would otherwise lead to a negative patient experience and poor compliance, in particular for pharmaceutical compositions that dissolve or disintegrate in the oral cavity. However, many of the materials used to coat APIs are hydrophobic. Thus, the coated API particles are hydrophobic.

[0006] To accurately dispense a pharmaceutical composition into a small, administrable form, a hydrophobic coated API particle can be placed in a matrix solution/suspension to form a pharmaceutical suspension. Mixing the API to form a pharmaceutical suspension allows for improved dosing accuracy. Oftentimes, this pharmaceutical suspension comprising the hydrophobic coated API particles can be dosed into molds, dried, and the molded article can then be transferred into a bottle, for example. However, this kind of handling of the pharmaceutical composition can increase risks such as damage and contamination.

[0007] Accordingly, many API suspensions today are dosed into preformed blister packs instead. Preformed blister packs eliminate one of the handling steps described above. Instead of dosing into a mold and then transferring the molded article to a bottle for packaging, preformed blister packs allow a manufacturer to dose the pharmaceutical suspension into a preformed blister pack that can be dried, then sealed and packaged. Thus, the preformed blister pack serves as both the mold and the package in which the pharmaceutical composition can be stored.

SUMMARY

[0007a] In a first aspect, the present disclosure refers to a method of making a pharmaceutical composition comprising:

providing a matrix solution/suspension comprising a matrix former, a structure former, 0.1-0.6 wt. % anti-aerating agent, and a solvent;

mixing a plurality of hydrophobic coated active pharmaceutical ingredient (API) particles into the matrix solution/suspension to form a pharmaceutical suspension, wherein the plurality of hydrophobic coated API particles comprises greater than 70 wt. % and no more than 90 wt. % of API; and

dosing the pharmaceutical suspension into preformed blister packs, wherein a dosed weight of the dosed pharmaceutical suspension is within 10% of a target dosed weight.

[0007b] In another aspect, the present disclosure refers to a pharmaceutical composition prepared by a process comprising the steps of:

providing a matrix solution/suspension comprising a matrix former, a structure former, an 0.1-0.6 wt. % anti-aerating agent, and a solvent;

mixing a plurality of hydrophobic coated active pharmaceutical ingredients (API) particles into the matrix solution/suspension to form a pharmaceutical suspension, wherein the plurality of hydrophobic coated API particles comprises greater than 70 wt. % and no more than 90 wt. % of API; and

dosing the pharmaceutical suspension into preformed blister packs, wherein a dosed weight of the dosed pharmaceutical suspension is within 10% of a target dosed weight.

[0007c] In yet another aspect, the present disclosure refers to a pharmaceutical composition disclosed herein, for use in administering to a patient.

[0007d] In a further aspect, the present disclosure refers to a pharmaceutical composition comprising:

a plurality of API particles;

a coating material encapsulating each API particle of the plurality of API particles, wherein the plurality of coated API particles comprises greater than 70 wt. % and no more than 90 wt. % of API;

a matrix former;

a structure former; and

an anti-aerating agent, wherein the pharmaceutical composition comprises from 1-5% w/w anti-aerating agent.

[0008] Provided are compositions and methods for preparing compositions that can minimize aeration of hydrophobic API particles in a pharmaceutical suspension. For example, hydrophobic coated API particles may be mixed into matrix solution/suspension to form a pharmaceutical suspension to accurately dose into molds to form solid pharmaceutical compositions (i.e., article, tablet, etc.) for administering to a patient. However, the

CLAIMS

1. A method of making a pharmaceutical composition comprising:

providing a matrix solution/suspension comprising a matrix former, a structure former, 0.1-0.6 wt.% anti-aerating agent, and a solvent;

mixing a plurality of hydrophobic coated active pharmaceutical ingredient (API) particles into the matrix solution/suspension to form a pharmaceutical suspension, wherein the plurality of hydrophobic coated API particles comprises greater than 70 wt. % and no more than 90 wt. % of API; and

dosing the pharmaceutical suspension into preformed blister packs, wherein a dosed weight of the dosed pharmaceutical suspension is within 10% of a target dosed weight.

2. The method of claim 1, wherein the dosed weight of the dosed pharmaceutical suspension is within 5% of a target dosed weight.

3. The method of claim 1, wherein the dosed weight of the dosed pharmaceutical suspension is within 2.5% of a target dosed weight.

4. The method of any of claims 1-3, wherein the coated API comprise one or more of anti-inflammatories, analgesics, anti-psychotics, anti-emetics, laxatives, anti-diarrheals, anti-histamines, or anti-depressants.

5. The method of any of claims 1-4, wherein the matrix solution/suspension comprises a viscosity modifier.

6. The method of claim 5, wherein the viscosity modifier comprises xanthan gum.

7. The method of any of claims 1-6, wherein mixing a plurality of hydrophobic particles into the matrix solution/suspension comprises in-line mixing at 15-20°C degrees Celsius.

8. The method of any of claims 1-7, wherein the anti-aerating agent comprises one or more of a terpene or a terpinol.

9. The method of any of claims 1-8, wherein the anti-aerating agent comprises a liquid flavor.

10. The method of any of claims 1-9, wherein the anti-aerating agent comprises a liquid flavor comprising limonene.

11. The method of any of claims 1-10, wherein the anti-aerating agent comprises one or more of orange flavor, lemon flavor, grapefruit flavor, lime flavor, strawberry flavor, or peppermint flavor.

12. The method of any of claims 1-11, wherein the matrix solution/suspension or pharmaceutical suspension comprises from 2.0-5.0 % w/w matrix former.

13. The method of any of claims 1-12, wherein the matrix suspension/solution or pharmaceutical suspension comprises from 1.0-5.0 % w/w structure former.

14. A pharmaceutical composition prepared by a process comprising the steps of:

providing a matrix solution/suspension comprising a matrix former, a structure former, an 0.1-0.6 wt. % anti-aerating agent, and a solvent;

mixing a plurality of hydrophobic coated active pharmaceutical ingredient (API) particles into the matrix solution/suspension to form a pharmaceutical suspension, wherein the plurality of hydrophobic coated API particles comprises greater than 70 wt. % and no more than 90 wt. % of API; and

dosing the pharmaceutical suspension into preformed blister packs, wherein a dosed weight of the dosed pharmaceutical suspension is within 10% of a target dosed weight.

15. The pharmaceutical composition of claim 14, wherein the dosed weight of the dosed pharmaceutical suspension is within 5% of a target dosed weight.

16. The pharmaceutical composition of claim 14, wherein the dosed weight of the dosed pharmaceutical suspension is within 2.5% of a target dosed weight.

17. The pharmaceutical composition of any of claims 14-16, wherein the coated API comprise one or more of one or more of anti-inflammatories, analgesics, anti-psychotics, anti-emetics, laxatives, anti-diarrheals, anti-histamines, or anti-depressants.

18. The pharmaceutical composition of any of claims 14-17, wherein the matrix solution/suspension comprises a viscosity modifier.

19. The pharmaceutical composition of claim 18, wherein the viscosity modifier comprises xanthan gum.

20. The pharmaceutical composition of any of claims 14-19, wherein mixing a plurality of hydrophobic particles into the matrix solution/suspension comprises in-line mixing at 15-20°C degrees Celsius.

21. The pharmaceutical composition of any of claims 14-20, wherein the anti-aerating agent comprises one or more of a terpene or a terpinol.

22. The pharmaceutical composition of any of claims 14-21, wherein the anti-aerating agent comprises a liquid flavor.

23. The pharmaceutical composition of any of claims 14-22, wherein the anti-aerating agent comprises a liquid flavor comprising limonene.

24. The pharmaceutical composition of any of claims 14-23, wherein the anti-aerating agent comprises one or more of orange flavor, lemon flavor, grapefruit flavor, lime flavor, strawberry flavor, or peppermint flavor.

25. The pharmaceutical composition of any of claims 14-24, wherein the matrix solution/suspension or pharmaceutical suspension comprises from 2.0-5.0 % w/w matrix former.

26. The pharmaceutical composition of any of claims 14-25, wherein the matrix solution/suspension or pharmaceutical suspension comprises from 1.0-5.0 % w/w structure former.

27. A pharmaceutical composition of any of claims 14-26, for use in administering to a patient.

28. The pharmaceutical composition for use of claim 27, wherein the patient is a human.

29. A pharmaceutical composition comprising:

a plurality of API particles;

a coating material encapsulating each API particle of the plurality of API particles, wherein the plurality of coated API particles comprises greater than 70 wt. % and no more than 90 wt. % of API;

a matrix former;

a structure former; and

an anti-aerating agent, wherein the pharmaceutical composition comprises from 1-5% w/w anti-aerating agent.

30. The pharmaceutical composition of claim 29, wherein the pharmaceutical composition is formed by creating a matrix solution/suspension comprising the matrix former, the structure former, and the anti-aerating agent.

31. The pharmaceutical composition of claim 29 or 30, wherein the plurality of API particles comprises one or more of one or more of anti-inflammatories, analgesics, anti-psychotics, anti-emetics, laxatives, anti-diarrheals, anti-histamines, or anti-depressants.

32. The pharmaceutical composition of any of claims 29-31, wherein the matrix solution/suspension comprises a viscosity modifier.

33. The pharmaceutical composition of claim 32, wherein the viscosity modifier comprises xanthan gum.

34. The pharmaceutical composition of any of claims 29-33, wherein the anti-aerating agent comprises one or more of a terpene or a terpinol.

35. The pharmaceutical composition of any of claims 29-34, wherein the anti-aerating agent comprises a liquid flavor.

36. The pharmaceutical composition of any of claims 29-35, wherein the anti-aerating agent comprises a liquid flavor comprising limonene.

37. The pharmaceutical composition of any of claims 29-36, wherein the anti-aerating agent comprises one or more of orange flavor, lemon flavor, grapefruit flavor, lime flavor, strawberry flavor, or peppermint flavor.

38. The pharmaceutical composition of any of claims 29-37, wherein the pharmaceutical composition comprises from 3-10 % w/w matrix former.

39. The pharmaceutical composition of any of claims 29-38, wherein the pharmaceutical composition comprises from 3-10 % w/w structure former.