additives) are dissolved or dispersed in solvent or water to form a suspension or solution. This suspension or solution may be sprayed onto the surface of the API particles to form a coating film upon 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. API 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 mouth.

[0006] For example, a dry, solventless mixing method may use high energy vibrations or acoustic resonance to mix the API with the inactive ingredient(s). Further, coating an API with a functional coating may temporarily delay the release of the API in a patient's mouth during dispersion of the pharmaceutical composition, yet still allow at least 90% of the API that would be released without the coating to be released from the functionally-coated API within a suitable amount of time for absorption. Coating the API in a taste-masking inactive ingredient allows the dissolution rate of the functionally-coated API to be controlled such that a majority of the API is not released until after the functionally-coated API has passed into a patient's stomach.

SUMMARY

[0006a] In an aspect of the present disclosure, there is provided a pharmaceutical composition comprising:

a coated API particle;

a first coating comprising one or more deformed components coating the API particle, wherein the one or more deformed components comprises 15-30 wt. % one or more of carnauba wax, candelilla wax, or synthetic wax;

a second coating comprising hydrophobic fumed silica on top of the first coating, wherein the coated API particle comprises 0.5-10 w.% hydrophobic fumed silica;

a matrix former; and

a structure former.

[0006b] In another aspect of the present disclosure, there is provided a pharmaceutical composition comprising:

coated API particles comprising:

a coated API particle;

a first coating comprising one or more deformed components coating the API particle, wherein the one or more deformed components comprises 15-30 wt.% one or more of carnauba wax, candelilla wax, or synthetic wax; and

a second coating comprising hydrophobic fumed silica on top of the first coating, wherein the coated API particle comprises 0.5-10 wt. % hydrophobic fumed silica;

a matrix former; and

a structure former,

wherein the pharmaceutical composition is prepared by mixing the coated API particles into a matrix solution/suspension comprising the matrix former and the structure former and a solvent to form a pharmaceutical suspension, and dosing the pharmaceutical suspension comprising the coated API particles into molds.

[0006c] In a further aspect of the present disclosure, there is provided a method of preparing a pharmaceutical composition comprising:

combining API particles with particles of a first coating material, wherein the first coating material comprises one or more deformable components;

applying energy to the combination of API particles and the particles of the first coating material to form an ordered mixture of API particles comprising a discrete layer of the particles of the first coating material on a surface of the API particles;

applying energy to the ordered mixture of API particles and particles of the first coating material to deform the one or more deformable components to form coated API particles, wherein the coated API particles comprise a continuous film of the first coating material surrounding each of the API particles;

combining the coated API particles with particles of a second coating material;

applying energy to the coated API particles with particles of the second coating material to at least partially embed the second coating material in the first coating material to form coated API particles comprising a second coating; and

mixing the coated API particles comprising the second coating into a matrix solution/suspension to form a pharmaceutical suspension.

[0007] Provided are pharmaceutical compositions and methods for preparing pharmaceutical compositions that are formulated to preserve the functional coating of a functionally-coated API particle during the manufacture process. Functionally-coated API particles are often mixed into a solution or suspension to form a pharmaceutical suspension. A pharmaceutical suspension allows for accurate dosing to form an administrable pharmaceutical product (i.e,

CLAIMS

1. A pharmaceutical composition comprising:

a coated API particle;

a first coating comprising one or more deformed components coating the API particle, wherein the one or more deformed components comprises 15-30 wt. % one or more of carnauba wax, candelilla wax, or synthetic wax;

a second coating comprising hydrophobic fumed silica on top of the first coating, wherein the coated API particle comprises 0.5-10 w.% hydrophobic fumed silica;

a matrix former; and

a structure former.

2. The pharmaceutical composition of claim 1, wherein the first coating is configured to mask a taste of the API particle.

3. The pharmaceutical composition of any of claims 1-2, wherein the matrix former comprises one or more of a water soluble material, a water dispersible material, a polypeptide, a polysaccharide, polyvinyl alcohol, polyvinylpyrrolidone, and acacia.

4. The pharmaceutical composition of any of claims 1-3, wherein the matrix former comprises a polypeptide.

5. The pharmaceutical composition of any of claims 1-4, wherein the matrix former comprises gelatin.

6. The pharmaceutical composition of any of claims 1-5, wherein the structure former comprises one or more of mannitol, dextrose, lactose, galactose, and cyclodextrin.

7. The pharmaceutical composition of any of claims 1-6, wherein the structure former comprises mannitol.

8. A pharmaceutical composition comprising:

coated API particles comprising:

a coated API particle;

a first coating comprising one or more deformed components coating the API particle, wherein the one or more deformed components comprises 15-30 wt.% one or more of carnauba wax, candelilla wax, or synthetic wax; and

a second coating comprising hydrophobic fumed silica on top of the first coating, wherein the coated API particle comprises 0.5-10 wt. % hydrophobic fumed silica;

a matrix former; and

a structure former,

wherein the pharmaceutical composition is prepared by mixing the coated API particles into a matrix solution/suspension comprising the matrix former and the structure former and a solvent to form a pharmaceutical suspension, and dosing the pharmaceutical suspension comprising the coated API particles into molds.

9. The pharmaceutical composition of claim 8, wherein the first coating is configured to mask a taste of the API particle.

10. The pharmaceutical composition of any of claims 8-9, wherein the matrix former comprises one or more of a water soluble material, a water dispersible material, a polypeptide, a polysaccharide, polyvinyl alcohol, polyvinylpyrrolidone, and acacia.

11. The pharmaceutical composition of any of claims 8-10, wherein the matrix former comprises a polypeptide.

12. The pharmaceutical composition of any of claims 8-11, wherein the matrix former comprises gelatin.

13. The pharmaceutical composition of any of claims 8-12, wherein the structure former comprises one or more of mannitol, dextrose, lactose, galactose, and cyclodextrin.

14. The pharmaceutical composition of any of claims 8-13, wherein the structure former comprises mannitol.

15. A method of preparing a pharmaceutical composition comprising:

combining API particles with particles of a first coating material, wherein the first coating material comprises one or more deformable components;

applying energy to the combination of API particles and the particles of the first coating material to form an ordered mixture of API particles comprising a discrete layer of the particles of the first coating material on a surface of the API particles;

applying energy to the ordered mixture of API particles and particles of the first coating material to deform the one or more deformable components to form coated API particles, wherein the coated API particles comprise a continuous film of the first coating material surrounding each of the API particles;

combining the coated API particles with particles of a second coating material;

applying energy to the coated API particles with particles of the second coating material to at least partially embed the second coating material in the first coating material to form coated API particles comprising a second coating; and

mixing the coated API particles comprising the second coating into a matrix solution/suspension to form a pharmaceutical suspension.

16. The method of claim 15, wherein the first coating material is configured to mask a taste of the API particle.

17. The method of claim 15 or 16, comprising dosing the suspension into preformed molds.

18. The method of any of claims 15-17, wherein the one or more deformable components of the first coating material comprises a wax.

19. The method of any of claims 15-18, wherein the wax comprises one or more of carnauba wax, candelilla wax, or synthetic wax.

20. The method of any of claims 15-19, wherein the second coating material comprises silica.

21. The method of any of claims 15-20, wherein the matrix solution/suspension comprises a matrix former and a structure former.

22. The method of claim 21, wherein the matrix former comprises one or more of a water soluble material, a water dispersible material, a polypeptide, a polysaccharide, polyvinyl alcohol, polyvinylpyrrolidone, and acacia.

23. The method of claim 21 or 22, wherein the matrix former comprises a polypeptide.

24. The method of any of claims 21-23, wherein the matrix former comprises gelatin.

25. The method of claim 21, wherein the structure former comprises one or more of mannitol, dextrose, lactose, galactose, and cyclodextrin.

26. The method of claim 21 or 25, wherein the structure former comprises mannitol.