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:

an API particle;

a first coating comprising one or more deformed components coating the API particle;

a second coating comprising silica on top of the first coating;

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:

an API particle;

a first coating comprising one or more deformed components; and

a second coating comprising 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,

pharmaceutical composition). Typically, shear forces required to incorporate the functionally-coated API particles into a suspension can cause the functional coating to erode. Erosion of this coating can destroy or damage the properties of the functional coating. Accordingly, functionally-coated API particles with an eroded coating can experience an increased dissolution rate and decreased taste-masking properties when orally administered to a patient.

[0008] However, pharmaceutical compositions and methods for preparing pharmaceutical compositions provided herein include preserving the coating of functionally-coated API particles in a pharmaceutical suspension with hydrophobic fumed silica. Specifically, the hydrophobic fumed silica can provide a protective layer surrounding and/or embedded into the functionally-coated API particle. In some examples, solventless processes for producing functionally-coated API particles may produce APIs comprising a first coating. According to some examples, hydrophobic fumed silica can be added during the solventless mixing process to produce a second, protective coating surrounding and/or partially or fully embedded into the functionally-coated API particles.

[0009] Additionally, the second, protective coating may limit the interaction between the functionally-coated API and the matrix solution/suspension such that impact of the functionally-coated API on the performance characteristics of the matrix is minimized.

[0010] In some examples, a pharmaceutical composition is provided, the pharmaceutical composition comprising an API particle; a first coating comprising one or more deformed components coating the API particle; a second coating comprising silica on top of the first coating; a matrix former; and a structure former. In some examples of the pharmaceutical composition, the first coating is configured to mask a taste of the API particle. In some examples, the pharmaceutical composition comprises 10-30 wt.% the first coating and 0.5-10 wt.% the second coating. In some examples, the pharmaceutical composition comprises 3-15 wt.% or 4-10 wt.% the structure former and/or 3-15 wt.% or 4-10 wt.% the matrix former. In some examples of the pharmaceutical composition, the one or more deformed components of the first coating comprises a wax. In some examples of the pharmaceutical composition, the wax comprises one or more of carnauba wax, candelilla wax, or synthetic wax. In some examples of the pharmaceutical composition, 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. In some examples of the pharmaceutical composition, the matrix former comprises a polypeptide. In some examples of the pharmaceutical composition, the matrix former comprises gelatin. In some examples of the pharmaceutical composition, the structure former comprises one or more of mannitol, dextrose, lactose, galactose, and

cyclodextrin. In some examples of the pharmaceutical composition, the structure former comprises mannitol.

[0011] In some examples, a pharmaceutical composition is provided, the pharmaceutical composition comprising coated API particles comprising: an API particle; a first coating comprising one or more deformed components; and a second coating comprising 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. In some examples of the pharmaceutical composition, the first coating is configured to mask a taste of the API particle. In some examples of the pharmaceutical composition, the one or more deformed components of the first coating material comprises a wax. In some examples of the pharmaceutical composition, the wax comprises one or more of carnauba wax, candelilla wax, or synthetic wax. In some examples of the pharmaceutical composition, 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. In some examples of the pharmaceutical composition, the matrix former comprises a polypeptide. In some examples of the pharmaceutical composition, the matrix former comprises gelatin. In some examples of the pharmaceutical composition, the structure former comprises one or more of mannitol, dextrose, lactose, galactose, and cyclodextrin. In some examples of the pharmaceutical composition, the structure former comprises mannitol.

[0012] In some examples, a method of preparing a pharmaceutical composition is provided, the method 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 to form coated API particles comprising a second coating; and mixing the coated API particles comprising a second coating into a matrix solution/suspension to form a pharmaceutical suspension. In some examples of the method, the first coating material is configured to mask a taste of the API particle. In some examples of the method, the methods comprises dosing the suspension into preformed molds. In some examples of the method, the one or more deformable components of the first coating material comprises a wax. In some examples of the method, the wax comprises one or more of carnauba wax, candelilla wax, or synthetic wax. In some examples of the method, the second coating material comprises silica. In some examples of the method, the matrix solution/suspension comprises a matrix former and a structure former. In some examples of the method, 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. In some examples of the method, the matrix former comprises a polypeptide. In some examples of the method, the matrix former comprises gelatin. In some examples of the method, the structure former comprises one or more of mannitol, dextrose, lactose, galactose, and cyclodextrin. In some examples of the method, the structure former comprises mannitol.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

[0014] Fig. 1A shows an API particle functionally-coated with particles of deformable coating material according to some embodiments;

[0015] Fig. 1B shows an API particle functionally-coated with a continuous film layer of deformable coating material (i.e., a first functional coating) according to some embodiments;

[0016] Fig. 1C shows an API particle functionally-coated with a continuous film layer of deformable coating material (i.e., a first functional coating) with particles of a second coating material surrounding and/or partially embedded and/or embedded in the surface of the continuous film layer (i.e., a second protective coating) according to some embodiments;

[0017] Fig. 2 shows a scanning electron microscope (SEM) image of an un-coated API particle;