blister pack serves as both the mold and the package in which the pharmaceutical composition can be stored.

SUMMARY

[0008a] In an aspect of the present disclosure, there is provided a pharmaceutical composition comprising:

65-85 % w/w coated active pharmaceutical ingredient (API), wherein the API coating comprises a first coating material and 0.5-5% w/w silica surrounding, partially embedded in, and/or embedded in the first coating material; and

3-15 % w/w matrix former.

[0008b] In another aspect of the present disclosure, there is provided a method of preparing a pharmaceutical composition comprising:

coating an active pharmaceutical ingredient (API) with a first coating material to form coated API, wherein the first coating material comprises one or more deformable components;

applying mechanical stress to the coated Ibuprofen to deform the one or more deformable components;

coating the coated API with a second coating material comprising silica;

applying mechanical stress to embed the second coating material onto the first coating material of the coated API;

after embedding the second coating material onto the first coating material of the coated API, sieving the coated API to remove excess first coating material, wherein the excess first coating material comprises first coating material not bound to the coated API;

forming a pharmaceutical suspension comprising the twice coated API and a matrix solution or suspension;

dosing the pharmaceutical suspension into a mold; and

freeze drying the dosed pharmaceutical suspension in the mold to form a pharmaceutical composition.

[0008c] In a further aspect of the present disclosure, there is provided a pharmaceutical composition prepared by a process comprising the steps of:

coating an active pharmaceutical ingredient (API) with a first coating material to form coated API, wherein the first coating material comprises one or more deformable components;

CLAIMS

1. A pharmaceutical composition comprising:

65-85 % w/w coated active pharmaceutical ingredient (API), wherein the API coating comprises a first coating material and 0.5-5% w/w silica surrounding, partially embedded in, and/or embedded in the first coating material; and

3-15 % w/w matrix former.

2. The pharmaceutical composition of claim 1, wherein the first coating material comprises a wax.

3. The pharmaceutical composition of claim 2, wherein the first coating material comprises one or more of carnauba wax, synthetic wax, or candelilla wax.

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

5. The pharmaceutical composition of claim 4, wherein the matrix former comprises a polypeptide.

6. The pharmaceutical composition of claim 5, wherein the polypeptide comprises gelatin.

7. The pharmaceutical composition of any of claims 1-6, comprising a structure former comprising one or more of mannitol, dextrose, lactose, galactose, and cyclodextrin.

8. The pharmaceutical composition of any of claims 1-7, comprising 0.01-0.2 % w/w viscosity modifier.

9. The pharmaceutical composition of claim 8, wherein the viscosity modifier comprises xanthan gum.

10. The pharmaceutical composition of any of claims 1-9, comprising 0.1-2 % w/w anti-aerating agent.

11. The pharmaceutical composition of claim 10, wherein the anti-aerating agent comprises one or more of a terpene or a terpinol.

12. The pharmaceutical composition of claim 11, wherein the anti-aerating agent comprises limonene.

13. The pharmaceutical composition of claim 12, wherein the anti-aerating agent comprises one or more of orange flavor, lemon flavor, grapefruit flavor, lime flavor, strawberry flavor, or peppermint flavor.

14. The pharmaceutical composition of any of claims 1-13, comprising a sweetener.

15. The pharmaceutical composition of any of claims 1-14, comprising a second coating material, the second coating material surrounding the first coating material and comprising 0.5-5 % w/w silica.

16. The pharmaceutical composition of any of claims 1-15, wherein the pharmaceutical composition has a disintegration time of 4 seconds or less for at least six months under storage conditions of at least 25ºC and at least 60% relative humidity.

17. The pharmaceutical composition of any of claims 1-15, wherein the pharmaceutical composition has a disintegration time of 4 seconds or less for at least six months under storage conditions of at least 30ºC and at least 65% relative humidity.

18. The pharmaceutical composition of any of claims 1-15, wherein the pharmaceutical composition has a disintegration time of 4 seconds or less for at least six months under storage conditions of at least 40ºC and at least 75% relative humidity.

19. The pharmaceutical composition of any of claims 1-18, wherein the API comprises Ibuprofen.

20. A method of preparing a pharmaceutical composition comprising:

coating an active pharmaceutical ingredient (API) with a first coating material to form coated API, wherein the first coating material comprises one or more deformable components;

applying mechanical stress to the coated Ibuprofen to deform the one or more deformable components;

coating the coated API with a second coating material comprising silica;

applying mechanical stress to embed the second coating material onto the first coating material of the coated API;

after embedding the second coating material onto the first coating material of the coated API, sieving the coated API to remove excess first coating material, wherein the excess first coating material comprises first coating material not bound to the coated API;

forming a pharmaceutical suspension comprising the twice coated API and a matrix solution or suspension;

dosing the pharmaceutical suspension into a mold; and

freeze drying the dosed pharmaceutical suspension in the mold to form a pharmaceutical composition.

21. The method of claim 20, wherein sieving the coated API comprises passing the coated API through a device comprising two or more sieves.

22. The method of claim 20 or 21, wherein sieving the coated API comprises sieving the coated API to an average particle size of 75 μm of greater.

23. The method of any of claims 20-22, wherein sieving the coated API comprises sieving the coated API to an average particle size of 200 μm or less.

24. The method of any of claims 20-23, wherein the API comprises Ibuprofen.

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

coating an active pharmaceutical ingredient (API) with a first coating material to form coated API, wherein the first coating material comprises one or more deformable components;

applying mechanical stress to the coated API to deform the one or more deformable components;

coating the coated API with a second coating material comprising silica;

applying mechanical stress to embed the second coating material onto the first coating material of the coated API;

after embedding the second coating material onto the first coating material of the coated API, sieving the coated API to remove excess first coating material, wherein the excess first coating material comprises first coating material not bound to the coated API;

forming a pharmaceutical suspension comprising the twice coated API and a matrix solution or suspension;

dosing the pharmaceutical suspension into a mold; and

freeze drying the dosed pharmaceutical suspension in the mold to form a pharmaceutical composition.

26. The pharmaceutical composition of claim 25, wherein the API comprises Ibuprofen.