(ii) when the active pharmaceutical ingredient is hydrophilic or lipophobic, dissolving the active pharmaceutical ingredient in a hydrophilic or lipophobic solvent, in a hydrophilic or lipophobic surfactant, or combination thereof;

(b) contacting the first mixture and a lipophilic or hydrophobic surfactant, wherein the surfactant is a self-emulsifying surfactant, to form a second mixture;

(c) contacting the second mixture with water and a hydrophilic or lipophobic surfactant to form a third mixture;

(d) contacting the third mixture with film forming ingredient to form a slurry; and

(e) casting the slurry on a substrate and curing to form the oral dissolvable film.

The present disclosure provides for an oral dissolvable film that includes: (a) active pharmaceutical ingredient; (b) surfactant; (c) solvent for the active pharmaceutical ingredient; (d) film matrix; and (e) water; wherein, (1) when the active pharmaceutical ingredient is lipophilic or hydrophobic: (i) the surfactant is lipophilic or hydrophobic, and (ii) the solvent for the active pharmaceutical ingredient is lipophilic or hydrophobic; and (2) when the active pharmaceutical ingredient is lipophobic or hydrophilic: (i) the surfactant is lipophobic or hydrophilic, and (ii) the solvent for the active pharmaceutical ingredient is lipophobic or hydrophilic.

CLAIMS

1. A method of forming an oral dissolvable film, the method comprising:

(a) dissolving an active pharmaceutical ingredient in a first solvent-system to form a first mixture, wherein:

(i) when the active pharmaceutical ingredient is lipophilic or hydrophobic, dissolving the active pharmaceutical ingredient in a lipophilic or hydrophobic solvent, in a lipophilic or hydrophobic surfactant, or combination thereof; or

(ii) when the active pharmaceutical ingredient is hydrophilic or lipophobic, dissolving the active pharmaceutical ingredient in a hydrophilic or lipophobic solvent, in a hydrophilic or lipophobic surfactant, or combination thereof;

(b) contacting the first mixture and a lipophilic or hydrophobic surfactant, wherein the surfactant is a self-emulsifying surfactant, to form a second mixture;

(c) contacting the second mixture with water and a hydrophilic or lipophobic surfactant to form a third mixture;

(d) contacting the third mixture with film forming ingredient to form a slurry; and

(e) casting the slurry on a substrate and curing to form the oral dissolvable film.

2. The method of claim 1, wherein the film forming ingredient comprises at least one of mucoadhesive polymer, plasticizer, binder, filler, bulking agent, saliva stimulating agent, stabilizing and thickening agent, gelling agent, flavoring agent, taste masking agent, coloring agent, pigment, lubricant, release modifier, adjuvant, sweetening agent, solubilizer & emulsifier, fragrance, emulsifier, surfactant, pH adjusting agent, buffering agent, lipid, glidant, stabilizer, antioxidant, anti-tacking agent, humectant, solvent, permeation enhancer, and preservative.

3. The method of claim 1, wherein the lipophilic or hydrophobic solvent comprises an oil.

4. The method of claim 1, wherein the hydrophilic or lipophobic solvent comprises an aqueous liquid.

5. The method of claim 1, wherein the curing is carried out in a hot air oven at an air temperature of between 38°C to 110°C.

6. The method of claim 1, wherein the curing is carried out in a hot air oven at an air temperature of between 45°C to 80°C.

7. The method of claim 1, wherein the curing is carried out in a hot air oven at an air temperature of 50°C–70°C.

8. The method of claim 1, wherein the curing is carried out at a speed of between 0.8 feet/min to 2.5 feet/min.

9. The method of claim 1, wherein the curing is carried out at a speed of between 0.8 feet/min to 1.0 feet/min.

10. The method of claim 1, wherein the curing is carried out at a speed of between 2.0 feet/min to 2.5 feet/min.

11. The method of claim 1, wherein the oral dissolvable film comprises:

(a) hydrophilic active pharmaceutical ingredient;

(b) water carrier for the hydrophilic active pharmaceutical ingredient;

(c) hydrophilic surfactant for the hydrophilic active pharmaceutical ingredient;

(d) one or more co–surfactants;

(e) one or more self–emulsifying surfactants;

(f) film matrix; and

(g) water.

12. The method of claim 1, wherein the oral dissolvable film is configured to self-emulsify within 20 seconds upon contact with an oral mucosal surface of a subject.

13. The method of claim 1, wherein the oral dissolvable film is configured to form an oil–in–water (O/W) emulsion within 20 seconds upon contact with an oral mucosal surface of a subject.

14. The method of claim 1, wherein the oral dissolvable film is configured to form an oil–in–water (O/W) emulsion having an average droplet size of 0.1 microns to 120 microns within 20 seconds upon contact with an oral mucosal surface of a subject.

15. The method of claim 1, wherein the oral dissolvable film is configured to form an oil–in–water (O/W) emulsion having an average droplet size of

d(10): 0.5-10 micron,

d(50): 1-20 micron, and

d(90): 15-100 micron

within 20 seconds upon contact with an oral mucosal surface of a subject.

16. The method of claim 1, wherein the oral dissolvable film is suitable for oral administration (PO), buccal administration, sublingual administration, or mucosal administration.

17. The method of claim 1, wherein the oral dissolvable film has a moisture content of 3–13 wt.%.

18. The method of claim 1, wherein the oral dissolvable film is configured to disintegrate within 15 minutes upon buccal administration to a subject.

19. The method of claim 1, wherein the oral dissolvable film is configured to disintegrate within 30 seconds upon oral (PO) administration to a subject.

20. The method of claim 1, wherein the oral dissolvable film is configured for in vitro disintegration within 30 seconds.

21. The method of claim 1, wherein the oral dissolvable film exhibits at least one pharmacokinetic parameter selected from, (i) Tmax of between 45 min to 120 min, (ii) Cmax of at least 3.5 ng/ml, and (iii) $AUC_{0\text{-}t}$ of at least 13 ng/hr/ml.

22. The method of claim 1, wherein the oral dissolvable film exhibits at least one pharmacokinetic parameter selected from, (i) Tmax of 1.5 hr, (ii) Cmax of 4.4 ng/ml, and (iii) AUC_{0-t} of 13.5 ng/hr/ml.

23. The method of claim 1, wherein the oral dissolvable film exhibits an in vivo dissolution time of no more than 20 minutes.

24. The method of claim 1, wherein the oral dissolvable film exhibits a bioavailability of at least 15%.

25. The method of claim 1, wherein the oral dissolvable film exhibits a stability of at least 96% after nine months as measured under 40ºC/75% RH accelerated conditions.