Claims

1. An orally disintegrating ~~dispersing~~ tablet comprising:

(i) about 1 mg to about 6 mg of fluticasone propionate; and

(ii) at least one disintegrant;

wherein upon administration a therapeutically effective amount of fluticasone propionate is deposited topically in the upper gastrointestinal tract, and

wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test. ~~less than or equal to 20 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract.~~

2. The orally disintegrating tablet of claim 1, comprising about 1 mg to about 2 mg of fluticasone propionate. ~~dispersing tablet of claim 1, wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.~~

3. The orally disintegrating tablet of claim 1, comprising about 3 mg of fluticasone propionate. ~~dispersing tablet of claim 2, wherein said tablet disintegrates within 30 seconds.~~

4. The orally disintegrating tablet of claim 1, comprising a sugar alcohol and/or saccharide. ~~dispersing tablet of any one of claims 1-3, further comprising an adhesive agent, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyarylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.~~

5. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise fluticasone propionate and at least one excipient, and the rapidly dispersing granules comprise the disintegrant and a sugar alcohol and/or saccharide. ~~dispersing tablet of claim 4,~~

~~wherein the adhesive agent and the budesonide or solvate or ester thereof are intimately associated.~~

6. The orally disintegrating tablet of claim 5, wherein the rapidly dispersing granules have an average particle size of less than about 300 µm, and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 µm.~~dispersing tablet of claim 1, wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.~~

7. The orally disintegrating tablet of claim 5, wherein the drug particles have an average particle size of about 100-400 µm.~~dispersing tablet of claim 6, wherein the at least one disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.~~

8. The orally disintegrating tablet of claim 5, the drug particles have an average particle size of about 100-400 µm, the rapidly dispersing granules have an average particle size of less than about 300 µm, and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 µm.~~dispersing tablet of claim 1, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.~~

9. The orally disintegrating tablet of claim 5, comprising about 1 mg to about 2 mg of fluticasone propionate.~~dispersing tablet of claim 1, which is free of lubricant.~~

10. The orally disintegrating tablet of claim 5, comprising about 3 mg of fluticasone propionate.~~dispersing tablet of claim 6, wherein the tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the budesonide or solvate or ester thereof, and the rapidly dispersing granules comprise the at least one disintegrant and a sugar alcohol and/or saccharide.~~

11. The orally disintegrating tablet of claim 8, comprising about 1 mg to about 2 mg of fluticasone propionate.~~dispersing tablet of claim 10, wherein the drug particles have an average particle size of less than 400 µm, the rapidly dispersing granules have an average particle size of less than 300 µm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than 30 µm; or wherein the budesonide or solvate or ester thereof is disposed over the surface of an excipient, the rapidly dispersing granules have an~~

~~average particle size of less than 300 µm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than 30 µm.~~

12. The orally disintegrating tablet of claim 8, comprising about 3 mg of fluticasone propionate.~~dispersing tablet of claim 10 or claim 11, wherein the tablet comprises a lyophilized matrix, wherein the lyophilized matrix comprises the budesonide or solvate or ester thereof in combination with at least one excipient.~~

13. The orally disintegrating tablet of claim 1, wherein the disintegrant is crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, or combinations thereof.~~dispersing tablet of claim 12, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.~~

14. The orally disintegrating tablet of claim 13, wherein the disintegrant is crospovidone.~~dispersing tablet of claim 6, comprising less than or equal to 20 mg of budesonide or a solvate or ester thereof, and the at least one disintegrant, wherein the tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.~~

15. The orally disintegrating tablet of claim 5, wherein the sugar alcohol and/or saccharide is mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol. lactose, sucrose, maltose, or combinations thereof.~~dispersing tablet of claim 14, wherein the tablet comprises 0.05-0.3 mg budesonide.~~

16. An orally disintegrating tablet of claim 15, wherein the sugar alcohol is mannitol.~~dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.~~

17. The orally disintegrating tablet of claim 5, wherein the ratio of disintegrant to sugar alcohol, saccharide or mixture thereof in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01.~~dispersing tablet for use according to claim 16, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.~~

18. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet disintegrates within 60 seconds when tested in simulated saliva fluid using the USP <701> Disintegration Test.~~dispersing tablet of claim 1 comprising from 0.01 mg to 20 mg budesonide.~~

19. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.~~dispersing tablet of claim 1 comprising from 2 mg to 20 mg budesonide.~~

20. An orally disintegrating tablet comprising:

(i) about 1 mg to about 3 mg of fluticasone propionate; and

(ii) rapidly dispersing granules comprising (a) at least one disintegrant and (b) at least one sugar alcohol, saccharide, or combination thereof;

wherein upon administration a therapeutically effective amount of the fluticasone propionate is deposited topically in the upper gastrointestinal tract, and

wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test.

21. The orally disintegrating tablet of claim 20, wherein the orally disintegrating tablet comprises drug particles comprising the fluticasone propionate and at least one excipient.

22. The orally disintegrating tablet of claim 21, wherein drug particles have an average particle size of about 100-400 µm, the rapidly dispersing granules have an average particle size of less than about 300 µm, the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 µm, and the ratio of disintegrant to sugar alcohol and/or saccharide in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01.

23. The orally disintegrating tablet of claim 22, wherein the disintegrant is crospovidone.

24. The orally disintegrating tablet of claim 23, wherein the sugar alcohol is mannitol.

25. The orally disintegrating tablet of claim 24, comprising about 1 mg to about 2 mg of fluticasone propionate.

26. The orally disintegrating tablet of claim 24, comprising about 3 mg of fluticasone propionate.

27. The orally disintegrating tablet of claim 26, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.

28. Use of the orally disintegrating tablet according to claim 1 in the manufacture of a medicament for treating eosinophilic esophagitis in patient in need thereof.

29. The use of claim 28, comprising about 1 mg to about 2 mg of fluticasone propionate.

30. The use of claim 28, comprising about 3 mg of fluticasone propionate.