

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising ~~microcapsules selected from a water suspendable co-granulate of~~ taste-masked immediate release microcapsules ~~or taste-masked immediate release co-granulated microcapsules, and mixtures thereof,~~ wherein said microcapsules comprise fexofenadine ~~and coated with~~ a water-insoluble polymer coating.
2. ~~The pharmaceutical composition of claim 1, wherein said microcapsules are taste-masked immediate release co-granulated microcapsules.~~
- 3.2. The pharmaceutical composition of claims 1-2, wherein said fexofenadine is crystalline fexofenadine.
- 4.3. The pharmaceutical composition of claims 1-3, wherein said fexofenadine is fexofenadine hydrochloride.
- 5.4. The pharmaceutical composition of claims 1-4, wherein said water-insoluble polymer is selected from the group consisting of ethylcellulose, polyvinyl acetate, cellulose acetate, cellulose acetate butyrate, ~~polyvinyl acetate,~~ ammonio-methacrylate copolymers and mixtures thereof.
- 6.5. The pharmaceutical composition of claims ~~5~~ 4, wherein said water-insoluble polymer is ethylcellulose.
- 7.6. The pharmaceutical composition of claims 1-6, wherein the weight of the water insoluble polymer of said microcapsules is from about 2% to about 40%.
8. ~~The pharmaceutical composition of claim 7, the weight of the water insoluble polymer of said microcapsules is from about 10% to about 20%.~~
9. ~~The pharmaceutical composition of claim 8, wherein the weight of the water insoluble polymer of said microcapsules is from about 13% to about 18%.~~
- 10.7. The pharmaceutical composition of claim 4.3, wherein said composition releases at least about 60% of said fexofenadine hydrochloride within 15 minutes in pH 6.8 JP 2nd fluid.

~~11. — The pharmaceutical composition of claim 10, wherein said composition releases at least about 80% of said fexofenadine hydrochloride within 15 minutes in pH 6.8 JP 2nd fluid.~~

~~12. — The pharmaceutical composition of claim 11, wherein said composition releases at least about 90% of said fexofenadine hydrochloride within 15 minutes in pH 6.8 JP 2nd fluid.~~

~~13. — The pharmaceutical composition of claim 12, wherein said composition releases at least about 95% of said fexofenadine hydrochloride within 15 minutes in pH 6.8 JP 2nd fluid.~~

~~14. — The pharmaceutical composition of claims 1-13, wherein said microcapsules further comprise a surfactant.~~

~~15.8.~~ The pharmaceutical composition of claim 14, wherein said microcapsules further comprise a surfactant, a glidant or an antisticking agent.

~~16. — The pharmaceutical composition of claims 14-15, wherein said surfactant is selected from the group consisting of sodium docusate, sorbitan oleate, sorbitan laurate and sodium lauryl sulfate.~~

~~17. — The pharmaceutical composition of claim 16, wherein said surfactant is sodium docusate.~~

~~18.9.~~ The pharmaceutical composition of claims 1-17, further comprising at least one inactive ingredient which is optionally granulated and/or at least one excipient.

~~19. — The pharmaceutical composition of claim 18, wherein said inactive ingredient is selected from the group consisting of sugar alcohol saccharide, granulated sugar alcohol, and granulated saccharide.~~

~~20. — The pharmaceutical composition of claim 18, wherein said inactive ingredient is sucrose, xanthan gum, cyclodextrin, and mixtures thereof.~~

~~21.10.~~ The pharmaceutical composition of claims 1-20, wherein said composition is in the form of a tablet, capsule or sachet.

~~22.~~ The pharmaceutical composition of ~~claims 1-20~~, wherein the co-granulated microcapsules consists of taste masked immediate release microcapsules, xanthan gum and sucrose, wherein the weight ratio of microcapsules to the (xanthan gum+ sucrose) is 1:7.

~~23.~~11. The pharmaceutical composition of ~~claims 17-22~~ claim 1, further comprising sodium docosate, and one or more granulated inactive ingredients;

wherein the weight ratio of the co-granulated microcapsules to the granulated inactive ingredient is 1:1.

~~24.~~12. The pharmaceutical composition of ~~claims 22-23~~ wherein said composition is in the form of sachet, claim 1, wherein the co-granulated microcapsules consist of taste masked immediate release microcapsules, xanthan gum and sucrose powder granulated together, wherein the weight ratio of the taste-masked immediate release microcapsules to sucrose powder is between 1:6 and 1:7.

13. The pharmaceutical composition of claim 12, wherein the co-granulated microcapsules consists of taste masked immediate release microcapsules, xanthan gum and sucrose, wherein the weight ratio of microcapsules to sucrose powder is about 1:7.

14. The pharmaceutical composition of claim 13, wherein the co-granulated microcapsules have a fine fraction below 125 μm of <5.0% and a fraction over 600 μm which is <10.0%.

15. The pharmaceutical composition of claim 13, wherein the co-granulated microcapsules have a fine fraction below 125 μm of <5.0% and a fraction over 600 μm of <5.0%.

~~25.~~16. A process for preparing the pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises taste-masked immediate release microcapsules comprising fexofenadine coated with a water-insoluble polymer, wherein said process comprises the steps of: (a) dissolving a water-insoluble polymer in an organic solvent; (b) suspending fexofenadine in said organic solvent; (c) applying a coating of said water-insoluble polymer onto said fexofenadine by phase separation; and (d) separating said microcapsules from said organic solvent.

~~26.~~17. The process of claim 25 16, wherein said fexofenadine is crystalline fexofenadine.

~~27.~~18. The process of claim 25 16, wherein said fexofenadine is fexofenadine hydrochloride.

~~28. The process of claim 27, further comprising the step (c) drying said separated microcapsules.~~

~~29.~~19. The process of claim ~~28~~ 18, further comprising the step of adding a phase inducer agent to said organic solvent to promote step (c).

~~30.~~20. The process of claim ~~29~~ 19, wherein said phase inducer agent is selected from the group consisting of polyethylene, polyisobutylene, butyl rubber, polybutadiene, organosilicon polymers, and paraffin.

~~31. The process of claim 30, wherein said phase inducer agent is polyethylene.~~

~~32.~~21. ~~A The process for preparing a taste-masked immediate-release pharmaceutical composition in form of sachets of claim 18, further comprising the following steps: (a) dissolving a water-insoluble polymer in an organic solvent; (b) suspending fexofenadine in said organic solvent; (c) applying a coating of said water-insoluble polymer onto said fexofenadine by phase separation; (d) separating said microcapsules from said organic solvent; (e) optional wetting of microcapsules; (f) co-granulating the microcapsules with at least one inactive ingredient; (g) separately granulating at least one inactive ingredient; h) mixing of co-granulate obtained in step (f) together with the granulated inactive ingredient obtained in step (g); (i) filling the bulk mixture of step (h) in sachets.~~

22. The process of claim 21, wherein the inactive ingredient of step f) is sucrose, and wherein the step f) is carried out in the presence of an aqueous binder solution comprising sucrose and xanthan gum.

23. The process of claim 22, wherein the weight ratio of sucrose to xanthan gum in the aqueous binder solution is between 5:0 to 15:05.

~~33. A method for treating an inflammation-related condition in an individual comprising administering to an individual in need thereof a pharmaceutical composition comprising taste-masked immediate-release microcapsules or taste-masked immediate-release co-granulated microcapsules, wherein said microcapsules comprise fexofenadine and a water-insoluble polymer coating.~~

~~34. The method of claim 33, wherein said fexofenadine is crystalline fexofenadine.~~

~~35.— The method of claims 33-34, wherein said fexofenadine is fexofenadine hydrochloride.~~

~~36.— The method of claim 33, wherein the weight of the water insoluble polymer of said microcapsules is from about 2% to about 40%.~~

~~37.— The method of claim 35, wherein the weight of the water insoluble polymer of said microcapsules is from about 10% to about 20%.~~

~~38.— The method of claim 37, wherein the weight of the water insoluble polymer of said microcapsules is from about 13% to about 18%.~~

~~39.— The method of claim 33-38, wherein said inflammation related condition is seasonal allergic rhinitis or chronic idiopathic urticaria.~~

~~40.— The method of claim 39, wherein said inflammation related condition is seasonal allergic rhinitis.~~

~~41.— The method of claim 39, wherein said inflammation related condition is chronic idiopathic urticaria.~~

~~42.— The method of claim 33-41, wherein said water insoluble polymer is selected from the group consisting of ethylcellulose, polyvinyl acetate, cellulose acetate, cellulose acetate butyrate, polyvinyl acetate, ammonio-methacrylate copolymers and mixtures thereof.~~

~~43.— The method of claim 42, wherein said water insoluble polymer is ethylcellulose.~~

~~44.— The method of claims 33-43, wherein said composition releases at least about 80% of said fexofenadine hydrochloride within 15 minutes in pH 6.8 JP 2nd fluid.~~

~~45.— The method of claim 44, wherein said composition releases at least about 90% of said fexofenadine hydrochloride within 15 minutes in pH 6.8 JP 2nd fluid.~~

~~46.— The method of claims 33-43, wherein said microcapsules further comprise a surfactant.~~

~~47. The pharmaceutical composition of claim 45, wherein said microcapsules further comprise a glidant or an antisticking agent.~~

~~48. The method of claim 47, wherein said surfactant is selected from the group consisting of sodium docosate, sorbitan oleate, sorbitan laurate and sodium lauryl sulfate.~~

~~49. The method of claim 48, wherein said surfactant is sodium docosate.~~

~~50. The method of claim 33-49, further comprising at least one inactive ingredient which is optionally granulated and/or at least one excipient.~~

~~51. The method of claim 50, wherein said inactive ingredient is selected from the group consisting of sugar alcohol, saccharide, granulated sugar alcohol, and granulated saccharide.~~

~~52. The method of claim 51, wherein said inactive ingredient is sucrose, xanthan gum, cyclodextrin, and mixtures thereof.~~

~~53. The method of claim 33-52, wherein said pharmaceutical composition is in the form of a tablet, capsule or sachet.~~

~~54. The method of claim 53, wherein said pharmaceutical composition is in the form of a sachet.~~