Claims

1. A mucosal patch comprising:

a drug-containing layer comprising electrospun fibers, wherein the electrospun fibers comprise:

a drug substance;

20% to 45% by weight polyvinylpyrrolidone,

20% to 45% by weight ammonio methacrylate copolymer type B; and

15% to 60% by weight polyethylene oxide;

and

a backing layer comprising poly(caprolactone).

~~Electrospun fibres containing:~~

~~i) a first and a second hydrophilic fibre-forming polymer that is soluble in a hydrophilic solvent,~~

~~ii) a bioadhesive substance that is slightly soluble in said hydrophilic solvent,~~

~~iv) a drug substance,~~

~~wherein the first hydrophilic polymer has a solubility in water at 37°C that is at least 10 times greater than the solubility in water at 37°C of the second hydrophilic fibre-forming polymer, and wherein the bioadhesive substance is present in solid form.~~

2. The mucosal patch according to claim 1, wherein the drug substance is a corticosteroid.

~~Electrospun fibres according to claim 1, wherein said first and the second hydrophilic fibre-forming polymer has a solubility in said hydrophilic solvent of 3 g/100 ml or more at 25 °C or 10 g/100 ml or more at 25 °C.~~

3. The mucosal patch according to claim 1, wherein the drug substance is clobetasol propionate.~~Electrospun fibres according to any of the preceding claims, wherein said hydrophilic solvent is selected from ethanol, or ethanol-water mixtures.~~

4. The mucosal patch according to claim 1 or 2, wherein the amount of ammonio methacrylate copolymer type B in the electrospun fibers is 25% to 45% by weight.~~Electrospun fibres according to claim 3, wherein said ethanol-water mixtures contain 20% v/v water or less or 10% v/v water or less.~~

5. The mucosal patch according to any one of claims 1-4, wherein the weight ratio of polyvinylpyrrolidone to ammonio methacrylate copolymer type B is 0.7 to 1..~~Electrospun fibres according to claim 3 or 4, wherein said ethanol-water mixtures contain 5% v/v water or less such as 3% v/v water of less.~~

6. The mucosal patch according to any one of claims 1-5, wherein the amount of polyvinylpyrrolidone and ammonio methacrylate copolymer type B in the electrospun fibers is 50% to 85% by weight.~~Electrospun fibres according to any of the preceding claims, wherein said first hydrophilic polymer has a solubility in water that is at least 50 times greater than the water solubility of said second hydrophilic polymer in water, both measured at 37°C.~~

7. The mucosal patch according to any one of claims 1-6, wherein the weight average molecular weight of the polyvinylpyrrolidone is 900,000 Da to 3,000,000 Da. ~~Electrospun fibres according to any of the preceding claims, wherein said first hydrophilic polymer has a solubility in water that is at least 100 times greater or at least 500 times than the water solubility of said second hydrophilic polymer in water, both measured at 37°C.~~

8. The mucosal patch according to any one of claims 1-7, wherein the weight average molecular weight of the polyvinylpyrrolidone is 1,500,000 Da.~~Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance is at the most very slightly soluble in said solvent selected from ethanol, or ethanol-water mixtures at a temperature of 25 °C.~~

9. The mucosal patch according to any one of claims 1-7, wherein the ammonio methacrylate copolymer type B is a copolymer of ethyl acrylate, methyl methacrylate, and trimethylammonioethyl methacrylate chloride in a molar ratio of 1: 2: 0.1.~~Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance has a solubility of at the most 0.1% w/w in said solvent selected from ethanol,ethanol-water mixtures at a temperature of 25 °C.~~

10. The mucosal patch according to any one of claims 1-9, wherein the ammonio methacrylate copolymer type B is a copolymer of ethyl acrylate, methyl methacrylate, and trimethylammonioethyl methacrylate chloride having a weight average molar mass of 32,000 g/mol.~~Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance has a solubility of at the most 0.01% w/w in said solvent selected from ethanol,ethanol-water mixtures at a temperature of 25 °C.~~

11. The mucosal patch according to any one of claims 1-10, wherein the average molecular weight of the polyethylene oxide is 100,000 to 4,000,000.
~~Electrospun fibres according to any of the preceding claims, wherein at least 90% w/w of the bioadhesive substance is present in solid form.~~

12. The mucosal patch according to any one of claims 11, wherein the amount of polyethylene oxide in the electrospun fibers is 15% to 50% by weight.~~Electrospun fibres according to any of the preceding claims, wherein at least 95% w/w or 99% w/w of the bioadhesive substance is present in solid form.~~

13. The mucosal patch according to any one of claims 1-12, wherein the amount of polyethylene oxide in the electrospun fibers is 50% by weight.~~Electrospun fibres according to any of the preceding claims, wherein said first hydrophilic polymer is selected from polyvinylpyrrolidone (PVP), hydroxypropylcellulose, and mixtures thereof.~~

14. The mucosal patch according to any one of claims 1-13, wherein the weight ratio of polyethylene oxide to polyvinylpyrrolidone and ammonio methacrylate copolymer type B is 0.8 to 1.~~Electrospun fibres according to any of the preceding claims, wherein said second hydrophilic polymer is selected from ethylcellulose, acrylates and acrylic copolymers (Eudragit®), and mixtures thereof~~

15. The mucosal patch according to any one of claims 1-14, wherein the poly(caprolactone) comprises melted electrospun poly(caprolactone) fibers. ~~Electrospun fibres according to any of the preceding claims, wherein the first hydrophilic polymer is PVP and the second hydrophilic polymer is Eudragit®.~~

16. The mucosal patch according to any one of claims 1-15, wherein the backing layer further comprises a pigment.~~Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance is selected from dextrans, polyethylene oxides (PEOs), alginate, tragacanth, carrageenan, pectin, gelatin, guar, xanthan, gellan, methylcellulose, hydroxypropylmethylcellulose (HPMC), polyvinylalcohol (PVA), polymers of acrylic acids (PAA derivatives), chitosan, lectins, thiolated polymers, polyoxo WSRA, PAA-co-PEG (PEG is polyethylene glycol), and mixtures thereof.~~

17. A kit comprising the mucosal patch of any one of claims 1-16.~~Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance is dextran having an average molecular weight of from 400,000 Da to 2,000,000 Da.~~

18. The mucosal patch according to any of claims 1-16 for use in the treatment of diseases of the oral or vaginal cavity.~~Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance is dextran having an average molecular weight of about 2,000,000 Da.~~

~~19. Electrospun fibres according to any of claims 1-16, wherein the bioadhesive substance is polyethylene oxide having an average molecular weight of from 100,000 Da to 4,000,000 Da.~~

~~20. Electrospun fibres according to any of claims 1-16, wherein the bioadhesive substance is polyethylene oxide having an average molecular weight of 2,000,000 Da.~~

~~21. Electrospun fibres according to any of the preceding claims, wherein the weight ratio between the bioadhesive substance and the hydrophilic fibre-forming polymers in the fibres is in a range of from 0.1 to 10.~~

~~22. Electrospun fibres according to any of the preceding claims, wherein the drug substance is selected from drug substances, which are indicated for treatment of a disease of the skin or mucosa.~~

~~23. Electrospun fibres according to any of the preceding claims, wherein the drug substance is selected from drug substances, which are indicated for treatment of a disease in the oral or vaginal cavity.~~

~~24. Electrospun fibres according to claim 23, wherein the drug substance is selected from drug substances, which are indicated for local treatment of a disease in the oral cavity.~~

~~25. Electrospun fibres according to any of the preceding claims, wherein the water content is at the most about 5% w/w.~~

~~26. Electrospun fibres according to any of the preceding claims for use in medicine.~~

~~27. Electrospun fibres according to any of the preceding claims for use in the treatment of diseases of the oral or vaginal cavity.~~

~~28. A composition comprising electrospun fibres as defined in any of claims 1-27.~~

~~29. A composition according to claim 28, wherein the concentration of the electrospun fibres in the composition is from 70 to 100% w/w.~~

~~30. A composition according to claim 28 or 29 in the form of a layered composition.~~

~~31. Electrospun fibres according to any one of claims 1-27 or a composition according to any one of claims 28-30, wherein an outer surface of said electrspun fibres or composition is provided with a coating.~~

~~32. Electrospun fibres or a composition according to claim 31, wherein the coating is water-impermeable.~~

~~33. Electrospun fibres or a composition according to claim 31 or 32, wherein the coating comprises carbothane, polycapronelactone or polyethylene-co-vinyl acetate, or mixtures thereof.~~

~~34. Electrospun fibres as defined in any of claims 1-27 or a composition as defined in any of claims 28-33 for use in medicine.~~

~~35. Electrospun fibres according to any of claim 1-27 or a composition as defined in any of claims 28-35 for use in the treatment of diseases of the oral cavity.~~

~~36. A kit comprising~~
~~i) elecrtrospun fibres or a composition as defined in any of the preceding claims, and~~
~~ii) an applicator for applying the composition in the oral cavity.~~

~~37. A method for preparing electrospun fibres as defined in any of claims 1-27, the method comprising~~
~~i) dissolving the first and the second hydrophilic polymer in a solvent selected from ethanol, or ethanol-water mixtures,~~
~~ii) suspending the bioadhesive substance in the resulting solution from step i),~~
~~iii) if relevant, adding the drug substance to the resulting dispersion from step ii),~~
~~iv) electrospinning the resulting mixture from step ii) or, if relevant step iii),~~
~~wherein said first and second hydrophilic polymer is soluble in said solvent, and said bioadhesive substance is slightly soluble or less in said solvent,~~
~~to obtain electrospun fibres, wherein at least 90% w/w of the bioadhesive substance is present in solid form.~~

~~38. A method for preparing electrospun fibres according to any of claims 1-27, the method comprising~~
~~i) dissolving the first and second hydrophilic polymer in a solvent selected from ethanol, water or mxtures thereof to obtain a first solution,~~
~~ii) if relevant, dissolving or suspending the drug substance in said solution to obtain a mixture,~~
~~iii) suspending the bioadhesive substance in the solvent to obtain a dispersion,~~
~~iiv) dual-electrospinning the mixture from step i), or if relevant step ii) and the dispersion from iii),~~
~~wherein said first and second hydrophilic polymer is soluble in said solvent, and said bioadhesive substance is slightly soluble in said solvent,~~
~~to obtain electrospun fibres, wherein at least 90% w/w of the bioadhesive substance is present in solid form.~~

~~39. A method according to claim 37 or 38 further comprising a step of coating an outer surface of the fibres with a hydrophobis polymer.~~

~~40. A method according to claim 39, wherein the coated fibres are subject to heating to melt or soften the hydrophobic polymer.~~