CLAIMS

1. A drug delivery system comprising a decellularized corneal stroma scaffold having dispersed within and/or bound to the surface microparticles containing at least one pharmaceutically active molecule dispersed in a matrix having a composition consisting for at least 70% of polylactic co-glycolic acid (PLGA).

2. A drug delivery system according to claim 1, wherein said corneal stroma scaffold is cell-free.

3. A drug delivery system according to claim 1 or 2, wherein said matrix comprises at least 75% (w/w), preferably 80% (w/w), more preferably 85% (w/w) of polylactic co-glycolic acid (PLGA) and/or said matrix comprises between 85% (w/w) and 95% (w/w), more preferably 89% (w/w), of polylactic co-glycolic acid (PLGA).

4. A drug delivery system according to any one of claims 1 or 3, wherein said matrix further contains polyethylene glycol, preferably low-molecular-weight grade polyethylene glycol, more preferably PEG400, albumin, preferably human serum albumin (HSA), and/or Trehalose.

5. A drug delivery system according to any one of claims 1 to 4, wherein said particles have a particle size distribution measured by laser diffraction technology between 1 and 15 µm, preferably between 1.5 and 10 µm, more preferably between 1.9 and 7 µm.

6. A drug delivery system according to any one of claims 1 to 5, wherein said corneal stroma scaffold is a graft obtained from a donor cornea.

7. A drug delivery system according to any one of claims 1 to 6, wherein said corneal stroma scaffold is a corneal stroma lenticule.

8. A drug delivery system according to claim 7, wherein said corneal stroma lenitcule is obtained from a donor cornea by refractive eye surgery, preferably refractive lenticule extraction (ReLEx) or femtosecond lenticule extraction (FLEx).

9. A drug delivery system according to claim 7 or 8, wherein said corneal lenticule has a thickness between 80 and 300 µm, preferably between 100 and 150 µm and/or a diameter between 4 and 9 mm, preferably between 5 and 8 mm, more preferably between 6 and 7 mm.

10. A drug delivery system according to any one of claims 1 to 9, wherein said pharmaceutically active molecule is a protein or a peptide.

11. A drug delivery system according to claim 10, wherein said pharmaceutically active molecule is a growth factor or a growth factor-mimetic peptide or protein.

12. A drug delivery system according to claim 10 or 11, wherein said pharmaceutically active molecule is a neurotrophin or a neurotrophin-mimetic peptide or protein.

13. A drug delivery system according to any one of claims 10 to 12, wherein said pharmaceutically active molecule is nerve growth factor or a nerve growth factor-mimetic peptide or protein.

14. A drug delivery system according to claim 13, wherein the amount of said nerve growth factor in said microparticles is between 30 and 100 ng, preferably between 50 and 90 ng, more preferably between 60 and 80 ng for each mg of microparticles.

15. Method for preparing a drug delivery system as claimed in any one of claims 1 to 14, comprising the following steps:

a. obtaining a corneal stroma scaffold, preferably a corneal stroma lenticule from a donor cornea;

b. removing cellular material from said scaffold, if present, thus obtaining a decellularized corneal stroma scaffold;

c. incubating said decellularized corneal stroma scaffold in a suspension of microparticles containing at least one pharmaceutically active molecule dispersed in a matrix having a composition consisting for at least 70% (w/w) of polylactic co-glycolic acid (PLGA).

16. Method as claimed in claim 15, wherein in step b. said cellular material is removed by incubating the corneal stroma scaffold in a solution of a surfactant.

17. Method as claimed in claim 16, wherein said surfactant is Sodium Dodecyl Sulfate, preferably at a concentration between 0.05 and 0.2%, preferably 0.1%.

18. Method as claimed in any one of claims 15 to 17, wherein said microparticles of step c. are obtained by the following steps:

a. preparing a water/oil emulsion containing the pharmaceutically active principle and polylactic co-glycolic acid.

b. preparing an aqueous solution containing of polyvinyl alcohol doped with the same organic solvent used in the oil phase of step a.

c. mixing the emulsion and solution prepared in a. and in b. and homogenizing, thus obtaining a water/oil/water emulsion.

d. evaporating the organic solvent, thus obtaining precipitation of microparticles;

e. recovering and washing the precipitated microparticles;

f. freeze-drying the microparticles.

19. A pharmaceutically active molecule for use in the treatment of ocular pathologies, preferably pathologies of the front of the eye, wherein said pharmaceutically active molecule is to be administered in a drug delivery system according to any one of claims 1 to 14.

20. Use of a pharmaceutically active molecule in the manufacture of a medicament for the treatment of ocular pathologies, preferably pathologies of the front of the eye, wherein said medicament is to be administered in a drug delivery system according to any one of claims 1 to 14.