channel approach to loading the device with the drug has a limited capacity for the drug.

Summary

In one aspect, there is provided a degradable, removable, pharmaceutical subcutaneous implant for the sustained release of one or more drugs in a subject, wherein the pharmaceutical implant is composed of a tube comprising an outer wall made of a degradable polymer completely surrounding a cavity, wherein the outer wall has a plurality of openings and wherein the cavity contains one or more sets of micro-particles, which micro-particles contain an active agent or a combination of two or more active agents, and wherein the size of the microparticles is selected such that the majority of the microparticles cannot pass through the openings, and wherein the microparticles are fabricated from a biocompatible, biodegradable polymer selected from aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylene oxalates, polyamides, poly(iminocarbonates), poly(orthoesters), polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes, and blends thereof.

Brief Description of the Figures.

Figure 1.

Poly(dioxanone) extruded and laser machined tube. Diameter of holes is 50 microns, the number of rows of holes is 40, the number of holes per row is 60. Total number of holes is 2400. Total length of tube is 30 mm and total length of tube containing holes is 20 mm. The internal diameter of the tube is 3 mm.

Figure 2.

Cross-section of a poly(dioxanone) tube that has been electrospun. The wall thickness is 500 microns. The inner diameter is 2 mm.

Figure 3.

Surface of a poly(dioxanone) tube that has been electrospun. Fibers are randomly oriented and size of openings formed by fiber network is in the range of 1 - 20 microns.

Figure 4.

Optical micrographs of microparticles containing 70% (w/w) TMC278 and 30% (w/w) PLGA 50/50 1A. Magnification is 100X.

Figure 5.

Optical micrograpgh of microparticles containing 70% (w/w) TMC114 and 30% (w/w) PLGA 50/50 2A. Magnification is 500x.

Description of the Invention

The present invention relates to a degradable, removable, pharmaceutical implant for the sustained release of one or more drugs in a subject, wherein the pharmaceutical implant is composed of a tube comprising an outer wall made of a degradable polymer completely surrounding a cavity, wherein the outer wall has a plurality of openings and wherein the cavity contains one or more sets of micro-particles, which micro-particles contain an active agent or a combination of two or more active agents, and wherein the size of the microparticles is selected such that the majority of the microparticles cannot pass through the openings.

The tube is composed of a degradable polymer. The microparticles contain an active ingredient or a combination of two or more active ingredients and are conceived such

We Claim:

1. A degradable, removable, pharmaceutical subcutaneous implant for the sustained release of one or more drugs in a subject, wherein the pharmaceutical implant is composed of a tube comprising an outer wall made of a degradable polymer completely surrounding a cavity, wherein the outer wall has a plurality of openings and wherein the cavity contains one or more sets of micro-particles, which micro-particles contain an active agent or a combination of two or more active agents, and wherein the size of the microparticles is selected such that the majority of the microparticles cannot pass through the openings, and wherein the microparticles are fabricated from a biocompatible, biodegradable polymer selected from aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylene oxalates, polyamides, poly(iminocarbonates), poly(orthoesters), polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes, and blends thereof.

2. The implant of claim 1, wherein the cavity contains two or more sets of micro-particles.

3. The implant of claim 1, wherein the microparticles are embedded in a hydrogel.

4. The implant of claim 1, wherein the degradable polymer of the tube is selected from aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylene oxalates, polyamides, poly(iminocarbonates), poly(orthoesters), polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes, and blends thereof.

5. The implant of claim 4, wherein the degradable polymer is selected from copolymers of lactide (which includes d-, 1- and meso lactic acid, and d-, 1- and meso lactide) and glycolide (including glycolic acid).

6. The implant of claim 4, wherein the degradable polymer is a homopolymer of poly(dioxanone).

~~7. The implant of claim 1, wherein the microparticles are fabricated from a biocompatible, biodegradable polymer selected from aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylene oxalates, polyamides, poly(iminocarbonates), poly(orthoesters), polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes, and blends thereof.~~

~~8~~7. The implant of claim ~~7~~1, wherein the polymer used to fabricate the microparticles is a biocompatible, biodegradable polymer selected from homopolymers and copolymers of lactide (which includes d-, 1- and meso lactic acid, and d-, 1- and meso lactide), glycolide (including glycolic acid), epsilon-caprolactone, p-dioxanone (1,4 – dioxan-2-one), and trimethylene carbonate (1, 3-dioxan-2-one).

~~9~~8. The implant of claim ~~7~~1, wherein the polymer used to fabricate the microparticles is a biocompatible, biodegradable polymer selected from copolymers of lactide (which includes d-, 1- and meso lactic acid, and d-, 1- and meso lactide) and glycolide (including glycolic acid).

~~10~~9. The implant of claim ~~7~~1, wherein the polymer used to fabricate the microparticles is a biocompatible, biodegradable polymer selected from a co-polymer of lactide and glycolide with a mole percent of lactide that ranges from 85% to 50%.

~~11~~10. The implant of any one of the preceding claims, wherein the microparticles contain at least one drug selected from an HIV inhibitor or an HCV inhibitor.

~~12~~11. The implant of claim 2, wherein one set of microparticles contains a NRTI and another set of microparticles contains an NNRTI.

~~13~~12. The implant of claim 2, wherein one set of microparticles contains a NNRTI and another set of microparticles contains a PI.

~~14~~13. The implant of any one of the preceding claims containing rilpivirine.