

CLAIMS

What is claimed is:

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1. A pulsatile delivery device of an active agent, the device comprising:
a tube inserted into a cavity of a punctal plug; and
one or more pulsatile delivery units arranged in a generally linear fashion
within the tube, wherein two or more pulsatile delivery units comprise a core
10 comprising the active agent and an encapsulation layer around the core.

2. The pulsatile delivery device of claim 1 wherein the one or more
pulsatile delivery units comprise water soluble encapsulated beads.

15 3. The pulsatile delivery device of claim 2 wherein the generally linear
arrangement of the pulsatile delivery units limits exposure of pulsatile delivery units to
tear fluid to one pulsatile delivery unit at a time.

4. The pulsatile delivery device of claim 2 further comprising a boundary
20 layer between a first pulsatile delivery unit and a second pulsatile delivery unit.

5. The pulsatile delivery device of claim 1 further comprising a boundary
layer between a pulsatile delivery unit and an opening in the cavity of the punctal plug.

25 6. The pulsatile delivery device of claim 5 wherein the boundary layer
comprises a biodegradable membrane.

7. The pulsatile delivery device of claim 5 wherein the boundary layer
comprises a semi-porous membrane.

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8. The pulsatile delivery device of claim 5 wherein the boundary layer
comprises a mesh.

9. The pulsatile delivery device of claim 2, wherein the active agent-containing material comprises poly(epsilon-caprolactone) and ethylene vinyl acetate.

5 10. The pulsatile delivery device of claim 9, wherein the poly(epsilon-caprolactone) and ethylene vinyl acetate are each present in an amount of about 50 weight percent.

10 11. The pulsatile delivery device of claim 2, wherein the tube comprises a first pulsatile delivery unit comprising a first active-agent containing material comprising a relatively low concentration of the active agent and a second pulsatile delivery unit comprising a second active-agent containing material comprising a relatively high concentration.

15 12. The pulsatile delivery device of claim 1 wherein the core comprises an active agent-containing material and a phase separated inclusion.

20 13. The pulsatile delivery device of claim 1 wherein the core comprises an active agent-containing material and a destabilizing inclusion.

14 20 14. The pulsatile delivery device of claim 1 wherein the core comprises an active agent-containing material and a stabilizing inclusion.

25 15. The pulsatile delivery device of claim 1 wherein the punctal plug additionally comprises a punctal plug body and a cavity within the punctal plug body.

30 16. The pulsatile delivery device of claim 15 wherein the punctal plug additionally comprises an access opening to the cavity from a position external to the body when the plug is inserted into a punctum.

17. The pulsatile delivery device of claim 15 wherein the punctal plug additionally comprises a seal across the opening to the cavity, blocking access to the cavity from a position external to the body when the plug is stored outside a punctum.

CLAIMS

What is claimed is:

1. A pulsatile delivery device of an active agent, the device comprising:

a tube inserted into a cavity of a punctal plug; and
two or more discrete pulsatile delivery units arranged in a generally linear fashion within the tube, wherein the two or more discrete pulsatile delivery units comprise a core comprising the active agent and an encapsulation layer surrounding the core, the discrete pulsatile delivery units are spaced apart from one another and in a generally linear arrangement are arranged to release from the tube multiple pulses of active agent, wherein each respective pulse of active agent comprises a generally equal volume of active agent and each respective pulse of active agent comprises a generally equal concentration of active agent.

2. The pulsatile delivery device of claim 1 wherein the one or more pulsatile delivery units comprise water soluble encapsulated beads.

3. The pulsatile delivery device of claim 2 wherein the generally linear arrangement of the pulsatile delivery units limits exposure of pulsatile delivery units to tear fluid to one pulsatile delivery unit at a time.

4. The pulsatile delivery device of claim 2 further comprising a boundary layer between a first pulsatile delivery unit and a second pulsatile delivery unit.

5. The pulsatile delivery device of claim 2, wherein the active agent-containing material comprises poly(epsilon-caprolactone) and ethylene vinyl acetate.

6. The pulsatile delivery device of claim 5, wherein the poly(epsilon-caprolactone) and ethylene vinyl acetate are each present in an amount of about 50 weight percent.

7. The pulsatile delivery device of claim 2, wherein the tube comprises a first pulsatile delivery unit comprising a first active-agent containing material comprising a relatively low concentration of the active agent and a second pulsatile delivery unit comprising a second active-agent containing material comprising a relatively high concentration.

8. The pulsatile delivery device of claim 2, additionally comprising an initial pulsatile delivery until delivering an amount of active agent greater than amounts of active agent delivered by subsequent delivery units.

9. The pulsatile delivery device of claim 1 further comprising a boundary layer between a pulsatile delivery unit and an opening in the cavity of the punctal plug.

10. The pulsatile delivery device of claim 9 wherein the boundary layer comprises a biodegradable membrane.

11. The pulsatile delivery device of claim 9 wherein the boundary layer comprises a semi-porous membrane.

12. The pulsatile delivery device of claim 9 wherein the boundary layer comprises a mesh.

13. The pulsatile delivery device of claim 1 wherein the core comprises an active agent-containing material and a phase separated inclusion.

14. The pulsatile delivery device of claim 1 wherein the core comprises an active agent-containing material and a destabilizing inclusion.

15. The pulsatile delivery device of claim 1 wherein the core comprises an active agent-containing material and a stabilizing inclusion.

16. The pulsatile delivery device of claim 1 wherein the punctal plug additionally comprises a punctal plug body and a cavity within the punctal plug body.

17. The pulsatile delivery device of claim 16 wherein the punctal plug additionally comprises an access opening to the cavity from a position external to the body when the plug is inserted into a punctum.

18. The pulsatile delivery device of claim 16 wherein the punctal plug additionally comprises a seal across the opening to the cavity, blocking access to the cavity from a position external to the body when the plug is stored outside a punctum.