WHAT IS CLAIMED IS:

1. An intravaginal drug delivery device comprising:

(a) a device body comprising a hydrophobic carrier material having at least one channel defining at least one opening to an exterior of the device body, the at least one channel being adapted to receive at least one drug-containing insert; and

(b) at least one drug-containing insert positioned in the at least one channel, the drug-containing insert containing a pharmaceutically effective amount of at least one drug and at least one water-soluble release enhancer in an amount ranging from 15% to 70% by weight of the at least one drug-containing insert, the at least one drug and the at least one water-soluble release enhancer being dispersed in an insert carrier material;

wherein the hydrophobic carrier material and the insert carrier material are the same or different, the at least one drug-containing insert is exposed on the exterior of the device body when the intravaginal drug delivery device is in use and the at least one drug-containing insert is arranged to maintain surface contact between the insert and the channel in use and to be removable from the device body.

2. The intravaginal drug delivery device of Claim 1, wherein the at least one drug is a macromolecular drug.

3. The intravaginal drug delivery device of Claim 1, wherein the at least one drug is a water-soluble drug and the at least one drug-containing insert contains the at least one water-soluble release enhancer in an amount ranging from 15% to 70% by

weight of the at least one drug-containing insert.

4. The intravaginal drug delivery device of any one of Claims 1 to 3, wherein the at least one drug is selected from proteins, RNA- or DNA-based molecules, vaccines, and combinations thereof.

5. The intravaginal drug delivery device of Claim 4, wherein the proteins are selected from antibodies, antigens, adrenocorticotropic hormone, angiotensin, beta-endorphin, blood factors, bombesin, calcitonin, calcitonin gene relating polypeptide, cholecystokinin-8, colony stimulating factors, desmopressin, endothelin, enkephalin, erythropoietins, gastrins, glucagon, human atrial natriuretic polypeptide, interferons, insulin, growth factors, growth hormones, interleukins, luteinizing hormone release hormone, monoclonal antibodies, melanocyte stimulating hormone, muramyl-dipeptide, neurotensin, oxytocin, parathyroid hormone, peptide T, secretin, somatomedins, somatostatin, thyroid stimulating hormone, thyrotropin releasing hormone, thyrotropin stimulating hormone, vasoactive intestinal polypeptide, and vasopressin.

6. The intravaginal drug delivery device of Claim 4, wherein the RNA- or DNA-based molecules are selected from oligonucleotides, aptamers, ribozymes, DNAzymes and small interfering RNAs.

7. The intravaginal drug delivery device of Claim 4, wherein the vaccines are selected from whole viral particles, recombinant proteins, subunit proteins, DNA

vaccines, plasmids, bacterial vaccines, polysaccharides and other vaccine vectors.

8. The intravaginal drug delivery device of any one of Claims 1 to 7, wherein the at least one drug comprises an amount ranging from 0.001% to 50% by weight of the insert.

9. The intravaginal drug delivery device of any one of Claims 1 to 8, comprising first and second channels and first and second drug-containing inserts positioned, in use, in the first and second channels, respectively, wherein the first and second drug-containing inserts comprise drugs that are the same or different.

10. The intravaginal drug delivery device of any one of Claims 1 to 8, comprising first, second and third channels, and first, second and third drug-containing inserts positioned, in use, in the first, second and third channels, respectively, wherein the first, second and third drug-containing inserts comprise drugs that are the same or different.

11. The intravaginal drug delivery device of any one of Claims 1 to 10, wherein the device body is partial or complete toroid shape.

12. The intravaginal drug delivery device of any one of Claims 1 to 11, wherein the hydrophobic carrier material is a polymeric material selected from a polydimethylsiloxane, a copolymer of dimethylsiloxane and methylvinylsiloxane, a polyurethane, and a poly(ethylene-co-vinyl acetate).

13. The intravaginal drug delivery device of any one of Claims 1 to 12, wherein the at least one water-soluble release enhancer is selected from the group consisting of sugars or their water-soluble salts; sugar alcohols; salts; glycols; water-soluble or water-swellable polysaccharides; organic acids; amino acids; proteins; nonionic surface active agents; bile salts; organic solvents; polyethylene glycols; fatty acid esters; hydrophilic polymers, and combinations thereof.

14. The intravaginal drug delivery device of Claim 13, wherein the at least one drug-containing insert contains from 15% to 55% of the at least one water-soluble release enhancer by weight of the at least one drug-containing insert.

15. The intravaginal drug delivery device of any one of Claims 1 to 14, wherein the insert carrier material is a polymeric material selected from a polydimethylsiloxane, a copolymer of dimethylsiloxane and methylvinylsiloxane, a polyurethane, and a poly(ethylene-co-vinyl acetate).

16. The intravaginal drug delivery device of any one of Claims 1 to 15, wherein the hydrophobic carrier material, the insert carrier material, or both the hydrophobic and the insert carrier materials comprise a silicone elastomer.

17. The intravaginal drug delivery device of any one of Claims 1 to 16, wherein the at least one drug-containing insert is a cylindrical rod.

18. The intravaginal drug delivery device of Claim 17, wherein the at least one drug-containing insert defines a right circular cylinder.

19. The intravaginal drug delivery device of Claim 17, wherein the at least one drug-containing insert is circular in transverse cross-section and extends radially outwardly through the device body.

20. The intravaginal drug delivery device of any one of Claims 1 to 19, wherein the at least one drug-containing insert has a cross-sectional diameter of from 0.5 mm to 8 mm.

21. The intravaginal drug delivery device of any one of Claims 1 to 20, wherein the at least one drug-containing insert has a length of from 2 mm to 30 mm.

22. The intravaginal drug delivery device of any one of Claims 1 to 21, wherein the cross-sectional diameter of the at least one drug-containing insert exceeds the cross-sectional diameter of the channel by at least 1 mm in all directions.

23. The intravaginal drug delivery device of any one of Claims 1 to 22, wherein the at least one drug-containing insert further comprises at least one pharmaceutically acceptable non-water-soluble release enhancer in an amount ranging from 1% to 25% by weight of the insert.

24. The intravaginal drug delivery device of any one of Claims 1 to 23, wherein

the device body further comprises at least one drug, particulate filler material, diffusion inhibitor, chemical penetration enhancer, water-soluble release enhancer or combination thereof.

25. The intravaginal drug delivery device of Claim 24, wherein the at least one drug in the device body is selected from the group consisting of contraceptives, pain and migraine agents, drugs for hormone replacement therapy, anxiety and depression agents, drugs for the treatment of premenstrual syndrome, drugs for the treatment of genito-urinary disorders, drugs for cervical ripening/induction of labor, antibacterials, antifungals, antimalarial agents, antiprotozoal agents, antiviral and antiretroviral agents, drugs for the treatment of endometriosis, anti-emetic drugs and osteoporosis drugs.

26. The intravaginal drug delivery device of Claim 24 or 25, wherein the at least one drug is present in the device body in an amount ranging from 0.005% to 65% by weight of the device body.

27. The intravaginal drug delivery device of Claim 24, wherein the water-soluble release enhancer in the device body is selected from the group consisting of sugars or their water-soluble salts; sugar alcohols; salts; glycols; water-soluble or water-swellable polysaccharides; organic acids; amino acids; proteins; nonionic surface active agents; bile salts; organic solvents; polyethylene glycols; fatty acid esters; and hydrophilic polymers, and combinations thereof.

28. The intravaginal drug delivery device of Claim 24 or 27, wherein the device body contains less than 10% of the water-soluble release enhancer by weight of the device body.

29. The intravaginal drug delivery device of any one of Claims 1 to 28, wherein the device body further comprises a sheath, provided that the at least one drug-containing insert is exposed on the exterior of the device body.

30. A method of preparing the intravaginal drug delivery device of any one of Claims 1 to 29 comprising the steps of:

(a) molding the hydrophobic carrier material in the form of the device body defining at least one channel; and

(b) inserting the at least one drug-containing insert into the at least one hollow internal channel such that the drug-containing insert is exposed on the exterior of the device body.

31. The method of Claim 30 further comprising the step of curing the device body.

32. The intravaginal drug delivery device of any one of Claims 1 to 29 for use in therapy.

CLAIMS

1. An intravaginal drug delivery device comprising:

(a) a device body comprising a hydrophobic carrier material having at least one channel defining at least one opening to an exterior of said device body, said at least one channel being adapted to receive at least one drug-containing insert; and

(b) at least one drug-containing insert positioned in said at least one channel, said drug-containing insert being capable of releasing a pharmaceutically effective amount of at least one drug suitable for intravaginal administration and containing at least one water-soluble release enhancer in an amount ranging from about 20% to about 70% by weight of said at least one drug-containing insert, said at least one drug and said at least one water-soluble release enhancer being dispersed in an insert carrier material;

wherein said hydrophobic carrier material and said insert carrier material may be the same or different;

wherein said at least one drug-containing insert is exposed on said exterior of said device body when said intravaginal drug delivery device is in use;

wherein said at least one drug-containing insert is arranged to maintain surface contact between said insert and said channel in use and to be removable from said device body;

wherein said at least one drug-containing insert defines a right circular cylinder, extends substantially perpendicular to the main plane of the device body, and has a cross-sectional diameter of from about 0.5 mm to about 8 mm; and

wherein the device body is a partial or complete toroid shape.

2. The intravaginal drug delivery device of claim 1, wherein said at least one drug is a macromolecular drug.

3. The intravaginal drug delivery device of claim 1, wherein said at least one drug is a water-soluble drug.

4. The intravaginal drug delivery device of claim 1, wherein said at least one drug is selected from proteins, RNA- or DNA-based molecules, vaccines, and combinations thereof.

5. The intravaginal drug delivery device of claim 4, wherein said proteins are selected from antibodies, antigens, adrenocorticotropic hormone, angiotensin, beta-endorphin, blood factors, bombesin, calcitonin, calcitonin gene relating polypeptide, cholecystokinin-8, colony stimulating factors, desmopressin, endothelin, enkephalin, erythropoietins, gastrins, glucagon, human atrial

natriuretic polypeptide, interferons, insulin, growth factors, growth hormones, interleukins, luteinizing hormone release hormone, monoclonal antibodies, melanocyte stimulating hormone, muramyl-dipeptide, neurotensin, oxytocin, parathyroid hormone, peptide T, secretin, somatomedins, somatostatin, thyroid stimulating hormone, thyrotropin releasing hormone, thyrotropin stimulating hormone, vasoactive intestinal polypeptide, vasopressin, and their analogues or derivatives.

6. The intravaginal drug delivery device of claim 4, wherein said RNA- or DNA-based molecules are selected from oligonucleotides, aptamers, ribozymes, DNAzymes and small interfering RNAs, for either vaccination against sexually transmitted infections or microbicidal activity against sexually transmitted microorganisms.

7. The intravaginal drug delivery device of claim 4, wherein said vaccines are selected from whole viral particles, recombinant proteins, subunit proteins, DNA vaccines, plasmids, bacterial vaccines, polysaccharides and other vaccine vectors.

8. The intravaginal drug delivery device of claim 1, wherein said at least one drug is employed in an amount ranging from about 0.001% to about 50% by weight of the insert.

9. The intravaginal drug delivery device of claim 1, comprising first and second channels and first and second drug-containing inserts positioned in said first and second channels, respectively, wherein said first and second drug-containing inserts comprise drugs that may be the same or different.

10. The intravaginal drug delivery device of claim 1, comprising first, second and third channels, and first, second and third drug-containing inserts positioned, in use, in said first, second and third channels, respectively, wherein said first, second and third drug-containing inserts comprise drugs that may be the same or different.

11. The intravaginal drug delivery device of claim 1, wherein said hydrophobic carrier material is a polymeric material selected from a polydimethylsiloxane, a copolymer of dimethylsiloxane and methylvinylsiloxane, a polyurethane, and a poly(ethylene-co-vinyl acetate).

12. The intravaginal drug delivery device of claim 1, wherein said at least one water-soluble release enhancer is selected from the group consisting of sugars or their water-soluble salts; sugar alcohols; salts; glycols; water-soluble or water-swellable polysaccharides; organic acids; amino acids; proteins; nonionic surface active agents; bile salts; organic solvents; polyethylene glycols; fatty acid

esters; hydrophilic polymers, and combinations thereof.

13. The intravaginal drug delivery device of claim 1, wherein said at least one drug-containing insert contains from about 15% to about 60% of said at least one water-soluble release enhancer by weight of said at least one drug-containing insert.

14. The intravaginal drug delivery device of claim 13, wherein said at least one drug-containing insert contains from about 15% to about 55% of said at least one water-soluble release enhancer by weight of said at least one drug-containing insert.

15. The intravaginal drug delivery device of claim 1, wherein the insert carrier material is a polymeric material selected from a polydimethylsiloxane, a copolymer of dimethylsiloxane and methylvinylsiloxane, a polyurethane, and a poly(ethylene-co-vinyl acetate).

16. The intravaginal drug delivery device of claim 1, wherein said hydrophobic carrier material, said insert carrier material, or both said hydrophobic and said insert carrier materials, comprise a silicone elastomer.

17. The intravaginal drug delivery device of claim 1, wherein said at least one drug-containing insert has a length of from about 2 mm to about 30 mm.

18. The intravaginal drug delivery device of claim 1, wherein the cross-sectional diameter of said at least one drug-containing insert exceeds the cross-sectional diameter of said channel by an average of about 1 mm in all directions.

19. The intravaginal drug delivery device of claim 1, wherein said at least one drug-containing insert further comprises at least one pharmaceutically acceptable non-water-soluble release enhancer in an amount ranging from about 1% to about 25% by weight of the insert.

20. The intravaginal drug delivery device of claim 1, wherein the device body further comprises at least one drug, particulate filler material, diffusion inhibitor, chemical penetration enhancer, water-soluble release enhancer or combination thereof.

21. The intravaginal drug delivery device of claim 20, wherein the at least one drug in the device body is selected from the group consisting of contraceptives, pain and migraine agents, drugs for hormone replacement therapy, anxiety and depression agents, drugs for the treatment of premenstrual

syndrome, drugs for the treatment of genito-urinary disorders, drugs for cervical ripening/induction of labor, antibacterials, antifungals, antimalarial agents, antiprotozoal agents, antiviral and antiretroviral agents, drugs for the treatment of endometriosis, anti-emetic drugs and osteoporosis drugs.

22. The intravaginal drug delivery device of claim 21, wherein the at least one drug is present in the device body in an amount ranging from about 0.005% to about 65% by weight of the device body.

23. The intravaginal drug delivery device of claim 20, wherein the water-soluble release enhancer in the device body is selected from the group consisting of sugars or their water-soluble salts; sugar alcohols; salts; glycols; water-soluble or water-swellable polysaccharides; organic acids; amino acids; proteins; nonionic surface active agents; bile salts; organic solvents; polyethylene glycols; fatty acid esters; and hydrophilic polymers, and combinations thereof.

24. The intravaginal drug delivery device of claim 20, wherein said device body contains less than about 10% of said water-soluble release enhancer by weight of said device body.

25. The intravaginal drug delivery device of claim 1, wherein the device body further comprises a sheath, provided that said at least one drug-containing insert is exposed on said exterior of said device body.

26. A method of preparing the intravaginal drug delivery device of claim 1 comprising the steps of:

(a) molding said hydrophobic carrier material in the form of said device body defining at least one channel; and

(b) inserting said at least one drug-containing insert into said at least one hollow internal channel such that said drug-containing insert is exposed on said exterior of said device body.

27. The method of claim 26 further comprising the step of curing the device body.

28. A method of preparing the intravaginal drug delivery device of claim 1 comprising the steps of:

(a) molding said hydrophobic carrier material in the form of said device body defining at least one channel;

(b) curing said insert material to form said at least one drug-containing insert; and

(c) inserting said at least one drug-containing insert into said at least one hollow internal channel such that said drug-containing insert is exposed on said exterior of said device body.