CLAIMS

1. A vaginal pharmaceutical composition comprising:

a) lactic acid at about 1.40 % w/w to about 2.5% w/w;

b) a mucoadhesive agent;

c) a viscosity of about 50 to about 150 Pa.s;

wherein the composition has an osmolality of 300 to 800 mOsm/Kg.

2. The composition of claim 1, wherein the composition comprises one or more of the following features:

i) lactic acid at about 1.64% w/w to about 2.25% w/w;

ii) about 18% to about 82% of the lactic acid is protonated;

iii) L-lactic acid;

iv) D-lactic acid;

v) D-lactic acid and L-lactic acid;

iv) D-lactic acid and L-lactic acid and a ratio of D-lactic acid to L-lactic acid selected from:

a) about 0.8 to 1 to about 1.5 to 1;

c) about 1 to 1; and

d) about 1.5 to 1.

3. The composition of claim 1 or claim 2, wherein the composition comprises an osmolality of about 300 to about 410 mOsm/Kg or wherein the composition comprises an osmolality selected of about 500 to about 800 mOsm/Kg.

4. The composition of any one of claims 1 to 3, wherein the composition comprises one or more of the following features:

i) the mucoadhesive agent is selected from one or more of: hydroxyethylcellulose (HEC) or a derivative thereof, a carbomer/a Carbopol®, methylhydroxypropyl cellulose, a hydrogel, and hydroxyproplyl methylcellulose;

ii) the composition comprises the mucoadhesive agent at a concentration of about 1% to about 3% w/w;

iii) the composition comprises the mucoadhesive agent at a concentration of about 1.32% w/w;

iv) the composition has a pH of about 3.2 to about 4.2;

v) the composition has a pH of about 3.7 to 3.8;

vi) the composition comprises one or more of: a paraben, sodium lactate and sodium chloride;

vii) the composition comprises a paraben, wherein the paraben is methylparaben and/or propylparaben;

viii) the composition comprises a paraben, wherein the paraben is present at a concentration of about 0.01 to about 0.2%, or about 0.02% to about 0.18%, or about 0.18%, or about 0.02%;

ix) the composition comprises a paraben, wherein the paraben is methylparaben and is present at about 0.18% w/w; and

x) the composition comprises a paraben, wherein the paraben in propylparaben and is present at about 0.02% w/w.

5. The composition of any one of claims 1 to 4, wherein the composition comprises one or more of the following features:

i) the composition is not cytotoxic to cervicovaginal epithelial cells;

ii) the composition does not disrupt the integrity of the cervicovaginal epithelial barrier and/or increases the integrity of the cervicovaginal epithelial barrier;

iii) the composition does not substantially increase the level of pro-inflammatory cytokines and/or pro-inflammatory chemokines;

iv) the composition reduces the level of pro-inflammatory cytokines and/or pro-inflammatory chemokines;

v) the composition does not substantially increase the expression of one or more pro-inflammatory cytokines selected from: IL-1α (interleukin 1 alpha), IL-1β (interleukin 1 beta) and IL-6 (interleukin 6);

vi) the composition reduces the expression of one or more pro-inflammatory cytokines selected from: IL-1α (interleukin 1 alpha), IL-1β (interleukin 1 beta) and IL-6 (interleukin 6);

vii) the composition does not substantially increase the expression of a pro-inflammatory chemokines selected from MIP3α (macrophage inflammatory protein-3 alpha), IL-8 (interleukin 8), IP-10 (IFN—gamma-inducible protein 10), and RANTES (regulated upon activation, normal T-cell expressed and presumably secreted);

viii) the composition does not substantially reduces the expression of a pro-inflammatory chemokines selected from MIP3α (macrophage inflammatory protein-3 alpha), IL-8 (interleukin 8), IP-10 (IFN—gamma-inducible protein 10), and RANTES (regulated upon activation, normal T-cell expressed and presumably secreted);

ix) the composition increases the expression of the anti-inflammatory factor interleukin-1 receptor antagonist (IL-1RA); and

x) the composition does not comprise one or more or all of: ethylenediaminetetraacetic acid (EDTA), glycerine/glycerol, polyethylene glycol (PEG), citric acid, organic aloe barbadensis leave juice, xantham gum, natural flavour, potassium sorbate, potassium bitartrate, acetic acid, butyric acid, succinic acid, boric acid, propylene glycol, caprylyl glycol, levulinic acid, P-anisic acid, xylose, clary sage oil, phenethyl alcohol, thymus mastichina herb oil, triethanolamine, hydrogenated castor oil ethoxylated, ethylparaben, propionic acid, sodium benzoate, chlorhexidine gluconate and sorbic acid.

6. The composition of any one of claims 1 to 5, wherein the composition comprises one or more of the following features:

i) is for daily administration;

ii) is for continuous, semi-continuous administration or periodic presumptive dosing;

iii) is in the form selected from a: gel, cream, capsule, ovule, lubricant or foam;

iv) is administered using a device selected from a: pessary, intravaginal ring, vaginal film, tampon, suppository, wipe or sponge;

v) a thermosensitive polymer;

vi) the pH of the composition was adjusted with sodium hydroxide or hydrochloric acid;

vii) is administered before, after or at the same time as one or more other therapeutic/s;

viii) is for treating or preventing genital inflammation in a subject; and

ix) is for treating or preventing cervicovaginal inflammation in a subject.

7. The composition of claim 6 viii), wherein the therapeutic is selected from:

i) is an antibiotic, hormone, contraceptive, a probiotic or a component thereof or a postbiotic;

ii) is a biotherapeutic, wherein the biotherapeutic is a bacteria or a part thereof selected from one or more or: *Lactobacillus, Leuconostoc, Bifidobacterium, Pediococcus, Lactococcus, Streptococcus, Aerococcus, Carnobacterium, Enterococcus, Oenococcus, Sporolactobacillus, Tetragenococcus, Vagococcus,* and *Weisella;* and

iii) is a biotherapeutic, wherein the biotherapeutic is the bacteria *Lactobacillus crispatus*, preferably *Lactobacillus crispatus* is CTV-05.

8. The composition of claim 6 ix), wherein the cervicovaginal inflammation is the cause or result of a condition selected from one or more of: bacterial vaginosis, *Chlamydia trachomatis*, gonorrhoea, human papillomavirus human immunodeficiency virus, trichomonas infection, vaginitis, pelvic inflammatory disease, allergy, ureaplasma, mycoplasma, campylobacter, syphilis, improper hygiene, douching/vaginal cleaning practices, and herpes simplex virus.

9. The composition of any one of claims 1 to 8, for use in maintaining or increasing the relative abundance of *Lactobacillus crispatus* in the cervicovaginal microbiome; for use in maintaining or increasing the relative abundance of *Lactobacillus gasseri* in the cervicovaginal microbiome; for use in maintaining or increasing the relative abundance of *Lactobacillus jensenii* in the cervicovaginal microbiome; for use in decreasing the relative abundance of *Lactobacillus iners* or *Gardnerella vaginalis* in the cervicovaginal microbiome; for use in increasing the ratio of *Lactobacillus crispatus* to *Lactobacillus iners*, the ratio of *Lactobacillus gasseri* to *Lactobacillus iners*, *Lactobacillus crispatus* to *Gardnerella vaginalis*, or *Lactobacillus jensenii* to *Lactobacillus iners* in the cervicovaginal microbiome; or for use in maintaining or increasing the integrity of the cervicovaginal epithelial barrier in a subject.

10. The composition of any one of claims 1 to 9, wherein the composition is an over the counter (OTC) composition.

11. A method of maintaining or increasing the relative abundance of one or more of *Lactobacillus crispatus*, of *Lactobacillus gasseri* and *Lactobacillus jensenii* in the cervicovaginal microbiome in a subject; a method of decreasing the relative abundance of *Lactobacillus iners* or *Gardnerella vaginalis* in the cervicovaginal microbiome in a subject; a method of increasing the ratio of *Lactobacillus crispatus* to *Lactobacillus iners* in the cervicovaginal microbiome in a subject; a method of increasing the integrity of the cervicovaginal epithelial barrier in a subject; or a method of maintaining or increasing the relative abundance of *Lactobacillus crispatus* in the urogenital tract microbiome in a subject, the method comprising administering the composition of any one of claims 1 to 10 to the subject.

12. Use of lactic acid at about 1.40 % w/w to about 2.5% w/w in the manufacture of a medicament for: treating or preventing cervicovaginal inflammation in a subject;

maintaining or increasing the relative abundance of *Lactobacillus crispatus* in the cervicovaginal microbiome in a subject; maintaining or increasing the relative abundance of *Lactobacillus gasseri* in the cervicovaginal microbiome in a subject; maintaining or increasing the relative abundance of *Lactobacillus jensenii* in the cervicovaginal microbiome in a subject; decreasing the relative abundance of *Lactobacillus iners* or *Gardnerella vaginalis* in the cervicovaginal microbiome in a subject; increasing the ratio of *Lactobacillus crispatus* to *Lactobacillus iners* in the cervicovaginal microbiome in a subject; maintaining or increasing the integrity of the cervicovaginal epithelial barrier in a subject; preventing a urogenital tract inflammation in a subject; or maintaining or increasing the relative abundance of *Lactobacillus crispatus* in the urogenital tract microbiome in a subject.

13. An applicator or device having the composition of any one of claims 1 to 10.

14. A vaginal delivery device comprising a pharmaceutical composition comprising lactic acid at about 1.40 % w/w to about 2.5% w/w, wherein the composition is iso-osmolal with cervicovaginal fluid or a vaginal delivery device comprising a pharmaceutical composition comprising lactic acid at about 1.40% w/w to about 4.5% w/w, wherein the composition has an osmolality of 300 to 800 mOsm/Kg.

15. A vaginal pharmaceutical composition comprising lactic acid at about 1.40 % w/w to about 4.5% w/w, wherein the composition has an osmolality of 300 to 800 mOsm/Kg.