## Claims

Having described the invention as previously mentioned, the following claims are claimed as property:

1. A pharmaceutical formulation in form of a solution, an emulsion or a nano-emulsion of 18β-glycyrrhetinic acid, characterized in that it comprises 18β-glycyrrhetinic acid in a concentration of 0.001% to 30% by weight of the formulation, wherein the formulation comprises a solubilizing agent selected from diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; a stabilizer selected from polyoxyglycerides, derivatives of castor oil or ethoxylated fatty alcohols; and an emollient oleaginous vehicle.

2. The formulation in accordance with claim 1, characterized in that it comprises 18β-glycyrrhetinic acid in a concentration of 0.01% to 5% by weight of the formulation.

3. The formulation in accordance with claims 1 or 2, characterized in that the solubilizing agent is 2-(2-ethoxyethoxy)-ethanol, wherein the stabilizer agent is a polyoxylglyceride selected of group of capric, lauric, linoleic, oleic acid or stearic acid triglycerides, an ethoxylated alcohol with the general structure $R-(OCH_2CH_2)_n-OH$

where R is an alkyl chain with a size from 12 to 18 carbons and n represents the moles of ethylene oxide, which may have a value of 2 to 25; or castor oil; and the oleaginous vehicle is isopropyl myristate.

4. The formulation in accordance with claim 1, characterized in that the percentages by weight of the components mentioned in claim 2 are: 0.001% to 30% of 18β-glycyrrhetinic acid; 40% to 60% for the diethylene glycol derivative; 1% to 15% for the polyoxylglyceride; 10% to 20% for the emollient oleaginous vehicle; 0% to 20% for the castor oil or its derivatives and 0% to 15% for ethoxylated fatty alcohol.

5. A method for preparing the formulation in accordance with claim 1, the method is characterized in that it comprises mixing the elements mentioned in claim 2, according to the proportions indicated in claim 3; heating the mixture in a range from 50 to 80 degrees Celsius, , adding the active ingredient in the proportion indicated in claim 2, stirring the mixture until the active ingredient is completely dissolved, allowing the solution to cool to room temperature.

6. The formulation according to claim 1, characterized in that the solution has a permeation of 0.6 µg/h/cm2.

7. The formulation in accordance with claim 1 wherein the formulation comprising an 18β-

glycyrrhetinic acid is an emulsion characterized in that it comprises additionally a cosurfactant element selected from ethoxylated fatty alcohols, and distilled water; wherein the solubilizing agent is 2-(2-ethoxyethoxy)-ethanol; the co-surfactant is an ethoxylated fatty alcohol with the general structure $R-(OCH_2CH_2)_n-OH$ where R is an alkyl chain with size of 12 to 18 carbons and n represents the moles of ethylene oxide, which can have a value of 2 to 25; the oleaginous vehicle is isopropyl myristate.

8. The formulation in accordance with claim 1 wherein the formulation comprising an 18β-glycyrrhetinic acid is a nano-emulsion characterized in that it comprises additionally a surfactant which may be a polyoxylglyceride; as well as castor oil or a derivative; and distilled water; wherein the solubilizing agent is 2-(2-ethoxyethoxy)-ethanol; the surfactant element is a polyoxylglyceride of capric, lauric, linoleic, oleic acid, or stearic acid triglycerides; the cosurfactant element can be an ethoxylated fatty alcohol with the general structure $R-(OCH_2CH_2)_n-OH$ where R is an alkyl chain with size from 12 to 18 carbons and n represents the moles of ethylene oxide, which can have a value from 2 to 25 or a castor oil derivative such as polyoxyethylenes from the castor oil and hydrogenated castor oils; and the emollient oleaginous vehicle is isopropyl myristate.

9. The formulation according to claim 7 characterized in that the percentages by weight of the components are: 0.001% to 30%, 40% to 60% for diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; 10% to 20% for emollient oleaginous vehicle; 0% to 20% for castor oil or its derivatives; 0% to 15% for ethoxylated fatty alcohol; and 5% to 50% for distilled water.

10. A method for preparing the formulation according to claim 7, the method is characterized in that it comprises mixing the components, described in percentage by weight of the components: 0.001% a 30%, of 18β-glycyrrhetinic acid; 40% to 60% for diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; 10% to 20% for the emollient oleaginous vehicle; 0% to 20% for castor oil or its derivatives; 0% to 15% for the ethoxylated fatty alcohol; and 5% to 50% for the distilled water, mixing first the 2-(2-ethoxyethoxy)-ethanol and isopropyl myristate; heating the mixture in the range from 50 to 80 degrees Celsius,; after reaching the desired temperature, stirring the mixture and adding the 18β-glycyrrhetinic acid until the active ingredient is completely dissolved, adding distilled water, stopping stirring and letting it cool down to room temperature.

11. The formulation in accordance with claim 7, characterized in that the resulting emulsion has a

permeation of 1.8 µg/h/cm², a particle size of 2500 nm, a hydrodynamic radius of 2850 nm, a diffusion coefficient of 1.26 µm²/s and a polydispersity of 39.8.

12. A gel characterized in that it comprises the formulation according to claims 1, 7 or 8, wherein the gel comprises gelling elements such as cellulose derivatives, e.g., hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HC) or hydroxypropyl methyl cellulose (HPmC), acrylic acid polymers or a member of the poloxamer family.

13. The gel in accordance with claim 12, characterized in that the gel comprises preservative and stabilizing agents selected from a group comprising butylated hydroxytoluene (BHT), butylated hydroxyanisole, L-cysteine, propylparaben, methylparaben, benzalkonium chloride, sodium benzoate and benzoic acid.

14. The formulation according to claim 8, characterized in that the percentages by weight of its components are: 0.001% to 30% of 18β-glycyrrhetinic acid; 40% to 60% for diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; 10% to 20% for emollient oleaginous vehicle; 0% to 20% for castor oil or its derivatives; 0% to 15% for ethoxylated fatty alcohol; and 5% to 50% for distilled water.

15. A method for preparing the formulation according to claim 8, the method is characterized

in that it comprises mixing the components described, in percentage by weight of the components: 0.001% to 30% of 18β-glycyrrhetinic acid; 40% to 60% for diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; 10% to 20% for the emollient oleaginous vehicle; 0% to 20% for castor oil or its derivatives; 0% to 15% for ethoxylated fatty alcohol; and 5% to 50% for distilled water, mixing first the diethylene glycol derivative, propylene glycol derivatives or polyethylene glycol derivatives, the emollient oleaginous vehicle, the castor oil or its derivatives and the ethoxylated fatty alcohol; heating the mixture in the range of 50 to 80 degrees Celsius,; stirring the mixture and adding 18β-glycyrrhetinic acid until completely dissolved, adding distilled water, stopping stirring and allowing to cool to room temperature.

16. The formulation according to claim 8, characterized in that it has a particle size of 1 to 100 nm, or from 500 to 1000 nm.

17. The formulation according to claim 8, characterized in that the permeation value of the nano-emulsion is of 0.6 to 8 $\mu g/h/cm^2$, wherein the nano-emulsion has a diffusion coefficient of a 0.003 to 1.5 $\mu m^2/s$ and a polydispersity of 2 to 50.

18. The formulation or gel according to any precedent claim, to be used in the treatment of viral infections, wherein the use as an antiviral drug is for the treatment of conditions caused by

human papillomavirus, such as low-grade and high-grade intraepithelial lesions and cervical cancer.

19. The formulation or gel according to any precedent claim, to be used in the treatment of cancer, wherein the use as an anticancer agent is for the treatment of cervical cancer.

# Claims

Having described the invention as previously mentioned, the following claims are claimed as property:

1. A pharmaceutical formulation comprising a **solution** of 18β-glycyrrhetinic acid, characterized in that it comprises 18β-glycyrrhetinic acid in a concentration of 0.001% to 30% by weight of the formulation, preferably in a concentration from 0.01% to 5% by weight of the formulation, wherein the formulation comprises a solubilizing agent selected from diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; a stabilizer selected from polyoxyglycerides, derivatives of castor oil or ethoxylated fatty alcohols; and an emollient oleaginous vehicle.

2. The formulation in accordance with claim 1, characterized in that the diluting agent is preferably 2-(2-ethoxyethoxy)-ethanol, wherein the stabilizer agent is preferably a polyoxylglyceride of capric, lauric, linoleic, oleic acid or stearic acid triglycerides, an ethoxylated alcohol with the general structure R-$(OCH_2CH_2)_n$-OH where R is an alkyl chain with a size from 12 to 18 carbons and n represents the moles of ethylene oxide, which may have a value of 2 to 25; or castor oil; and the oleaginous vehicle is preferably isopropyl myristate.

3. The formulation in accordance with claim 1, characterized in that the percentages by weight of the components mentioned in claim 2 are: 0.001% to 30%,

preferably in a percentage of 0.01% to 5% of 18β-glycyrrhetinic acid; 40% to 60% for the diethylene glycol derivative; 1% to 15% for the polyoxylglyceride; 10% to 20% for the emollient oleaginous vehicle; 0% to 20% for the castor oil or its derivatives and 0% to 15% for ethoxylated fatty alcohol.

4. A method for preparing the formulation in accordance with claim 1, the method is characterized in that it comprises mixing the various elements mentioned in claim 2, according to the proportions indicated in claim 3; heating the mixture in a range from 50 to 80 degrees Celsius, preferably from 60 to 70 degrees Celsius, adding the active ingredient in the proportion indicated in claim 2, stirring the mixture until the active ingredient is completely dissolved, allowing the solution to cool to room temperature.

5. The formulation according to claim 1, characterized in that the solution has a permeation of 0.6 µg/h/cm2.

6.The formulation in accordance with claim 1, to be used in the treatment of viral infections, wherein the use as an antiviral is preferably for the treatment of conditions caused by the virus of the human papilloma, such as low-grade and high-grade intraepithelial lesions and cervical cancer.

7. The formulation in accordance with claim 1, to be used in the treatment of cancer, wherein the use as an anticancer agent is preferably for the cervical cancer treatment.

8. A pharmaceutical formulation comprising an 18β-glycyrrhetinic acid **emulsion**, characterized in that it

comprises glycyrrhetinic acid in a concentration of 0.001 to 30% by weight of the formulation, preferably in a concentration of 0.01 to 5% by weight of the formulation, wherein the formulation comprises 18β-glycyrrhetinic acid, a solubilizing agent selected from diethylene glycol derivatives, propylene glycol derivatives, or polyethylene glycol derivatives; a cosurfactant element selected from ethoxylated fatty alcohols, or from castor oil and its derivatives; an emollient oleaginous vehicle and distilled water.

9. The formulation in accordance with claim 8, characterized in that the solubilizing agent is 2-(2-ethoxyethoxy)-ethanol; the co-surfactant is an ethoxylated fatty alcohol with the general structure R-$(OCH_2CH_2)_n$-OH where R is an alkyl chain with size of 12 to 18 carbons and n represents the moles of ethylene oxide, which can have a value of 2 to 25; the oleaginous vehicle is preferably isopropyl myristate.

10. The formulation according to claim 8 characterized in that the percentages by weight of the components are: 0.001% to 30%, preferably in a percentage of 0.01% to 5% of 18β-glycyrrhetinic acid; 40% to 60% for diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; 10% to 20% for emollient oleaginous vehicle; 0% to 20% for castor oil or its derivatives; 0% to 15% for ethoxylated fatty alcohol; and 5% to 50% for distilled water.

11. A method for preparing the formulation according to claim 8, the method is characterized in that it comprises mixing the components, described in percentage by weight of the components: 0.001% a 30%, preferably in

a percentage of 0.01% to 5%, of 18β-glycyrrhetinic acid; 40% to 60% for diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; 10% to 20% for the emollient oleaginous vehicle; 0% to 20% for castor oil or its derivatives; 0% to 15% for the ethoxylated fatty alcohol; and 5% to 50% for the distilled water, mixing first the 2-(2-ethoxyethoxy)-ethanol and isopropyl myristate; heating the mixture in the range from 50 to 80 degrees Celsius, preferably from 60 to 70 degrees Celsius; after reaching the desired temperature, stirring the mixture and adding the 18β-glycyrrhetinic acid until the active ingredient is completely dissolved, adding distilled water, stopping stirring and letting it cool down to room temperature.

12. The formulation in accordance with claim 8, characterized in that the resulting emulsion has a permeation of 1.8 μg/h/cm², a particle size of 2500 nm, a hydrodynamic radius of 2850 nm, a diffusion coefficient of 1.26 μm²/s and a polydispersity of 39.8.

13. The formulation in accordance with claim 8, to be used in the treatment of viral infections, wherein the use as an antiviral is preferably for the treatment of conditions caused by human papillomavirus, such as low- and high-grade intraepithelial lesions and cervical cancer.

14. The formulation in accordance with claim 8, to be used in the treatment of cancer, wherein the use as an anticancer drug is preferably for the treatment of cervical cancer.

15. A **gel** characterized in that it comprises the formulation according to claim 8, wherein the gel

comprises gelling elements such as cellulose derivatives, e.g., hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HC) or hydroxypropyl methyl cellulose(HPmC), acrylic acid polymers or a member of the poloxamer family.

16. The gel in accordance with claim 15, characterized in that the gel comprises preservative and stabilizing agents selected from a group comprising butylated hydroxytoluene (BHT), butylated hydroxyanisole, L-cysteine, propylparaben, methylparaben, benzalkonium chloride, sodium benzoate and benzoic acid.

17. The gel in accordance with claim 15, to be used in the treatment of viral infections, wherein the use as an antiviral is preferably for the treatment of conditions caused by human papillomavirus, such as low- and high-grade intraepithelial lesions and cervical cancer.

18. The gel in accordance with claim 15, to be used in the treatment of cancer, wherein the use as an anticancer agent is preferably for the treatment of cervical cancer.

19. A pharmaceutical formulation comprising a **nano-emulsion** comprising 18β-glycyrrhetinic acid, characterized in that the 18β-glycyrrhetinic acid is at a concentration of 0.001 to 30% by weight of the nano-emulsion, preferably at a concentration of 0.01 to 5% by weight of the nano-emulsion, wherein the nano-emulsion comprises a solubilizing agent which is a diethylene glycol derivative; a surfactant which may be a polyoxylglyceride; a cosurfactant which may be one or more ethoxylated fatty alcohols, their derivatives, as

well as castor oil or a derivative; an emollient oleaginous vehicle and distilled water.

20. The formulation according to claim 19, characterized in that the solubilizing agent is 2-(2-ethoxyethoxy)-ethanol; the surfactant element is a polyoxylglyceride of capric, lauric, linoleic, oleic acid, or stearic acid triglycerides; the cosurfactant element can be an ethoxylated fatty alcohol with the general structure $R-(OCH_2CH_2)_n-OH$ where R is an alkyl chain with size from 12 to 18 carbons and n represents the moles of ethylene oxide, which can have a value from 2 to 25 or a castor oil derivative such as polyoxyethylenes from the castor oil and hydrogenated castor oils; and the emollient oleaginous vehicle is isopropyl myristate.

21. The formulation according to claim 19, characterized in that the percentages by weight of its components are: 0.001% to 30%, preferably in a percentage of 0.01% to 5% of 18β-glycyrrhetinic acid; 40% to 60% for diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives; 10% to 20% for emollient oleaginous vehicle; 0% to 20% for castor oil or its derivatives; 0% to 15% for ethoxylated fatty alcohol; and 5% to 50% for distilled water.

22. A method for preparing the formulation according to claim 19, the method is characterized in that it comprises mixing the components described, in percentage by weight of the components: 0.001% to 30%, preferably in a percentage of 0.01% to 5% of 18β-glycyrrhetinic acid; 40% to 60% for diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol

derivatives; 10% to 20% for the emollient oleaginous vehicle; 0% to 20% for castor oil or its derivatives; 0% to 15% for ethoxylated fatty alcohol; and 5% to 50% for distilled water, mixing first the diethylene glycol derivative, propylene glycol derivatives or polyethylene glycol derivatives, the emollient oleaginous vehicle, the castor oil or its derivatives and the ethoxylated fatty alcohol; heating the mixture in the range of 50 to 80 degrees Celsius, preferably from 60 to 70 degrees Celsius; stirring the mixture and adding 18β-glycyrrhetinic acid until completely dissolved, adding distilled water, stopping stirring and allowing to cool to room temperature.

23. The formulation according to claim 22, characterized in that it has a particle size of 1 to 100 nm, preferably 1 to 20 nm, or from 500 to 1000 nm, preferably 600 to 700 nm.

24. The formulation according to claim 19, characterized in that the permeation value of the nano-emulsion is of 0.6 to 8 μg/h/cm$^2$, wherein the nano-emulsion has a diffusion coefficient of a 0.003 to 1.5 μm$^2$/s and a polydispersity of 2 to 50.

25. The formulation according to claim 19, to be used in the treatment of viral infections, wherein the use as an antiviral is preferably for the treatment of conditions caused by the human papillomavirus, such as low-grade and high-grade intraepithelial lesions and cervical cancer.

26.The formulation according to claim 19, to be used in the treatment of cancer, wherein the use as an anticancer agent is preferably for cervical cancer

treatment.

27. A gel characterized in that it comprises the formulation according to claim 19, wherein the gel comprises gelling elements such as cellulose derivatives, for example, hydroxypropyl cellulose (HPC),hydroxyethyl cellulose (HC) or hydroxypropyl methyl cellulose (HPmC), acrylic acid polymers or a member of the poloxamer family.

28. The gel in accordance with claim 27, characterized in that the gel comprises preservative and stabilizing agents selected from a group comprising butylated hydroxytoluene (BHT), butylated hydroxyanisole, L-cysteine, propylparaben, methylparaben, benzalkonium chloride, sodium benzoate and benzoic acid.

29. The gel according to claim 27, to be used in the treatment of viral infections, wherein the use as an antiviral drug is preferably for the treatment of conditions caused by human papillomavirus, such as low-grade and high-grade intraepithelial lesions and cervical cancer.

30. The gel in accordance with claim 27, to be used in the treatment of cancer, wherein the use as an anticancer agent is preferably for the treatment of cervical cancer.