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 an emulsion of 18β-glycyrrhetinic acid in a concentration of 0.~~0~~01% to 30% by weight ~~of the formulation~~, wherein the formulation comprises additionally ~~a solubilizing agent selected from diethylene glycol derivatives, propylene glycol derivatives or polyethylene glycol derivatives~~ 2-(2-ethoxyethoxy)-ethanol from 40% to 71%; at least a stabilizer selected ~~from polyoxyglycerides,~~ of polyoxyglyceride of capric, lauric, linoleic, oleic acid, or stearic acid triglycerides;

one or more of 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;

~~derivatives of~~ castor oil or hydrogenated castor oil ~~ethoxylated fatty alcohols~~; ~~and~~ an emollient oleaginous vehicle; and

distilled water.

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

3.- The formulation in accordance with claim~~s~~ 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$_2$CH$_2$)$_n$-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 emollient oleaginous vehicle is isopropyl myristate.

4.- The formulation in accordance with claim 1 or 3, characterized in that the percentages by weight of the components mentioned ~~in claim 2~~ are: 0.~~0~~01% to 30% of 18β-glycyrrhetinic acid; 40% to 60% for~~ the diethylene glycol derivative~~2-(2-ethoxyethoxy)-ethanol;~~ 1% to 15% for the polyoxylglyceride~~; 10% to 20% for the emollient oleaginous vehicle; 0% to 20% for the castor oil or ~~its derivatives~~ hydrogenated castor oil and 0% to 15% for ethoxylated fatty alcohol; and 5% to 50% for distilled water.

5. A method for preparing the formulation in accordance with claim 1, the method is

characterized in that it comprises mixing the components, described in percentage by weight of the components: 0.01% ~~a~~to 30% of 18β-glycyrrhetinic acid; 40% to 71% 2-(2-ethoxyethoxy)-ethanol; 10% to 20% for the emollient oleaginous vehicle; 0% to 20% for castor oil or hydrogenated castor oil; 0% to 15% for the ethoxylated fatty alcohol; and 5% to 50% for the distilled water; mixing first the 2-(2-ethoxyethoxy)-ethanol and emollient oleaginous vehicle, ~~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~~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.

~~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.~~

6~~11~~. The formulation in accordance with claims 1 to 4~~7~~, characterized in that the ~~resulting~~ emulsion has a permeation of 1.8 µg/h/cm^2, a particle size of 2500 nm, a hydrodynamic radius of 2850 nm, a diffusion coefficient of 1.26 µm^2/s and a polydispersity of 39.8.

7~~12~~.- A **gel** characterized in that it comprises the formulation according to claims 1 to 4~~, 7 or 8~~, wherein the gel comprises gelling elements such as cellulose derivatives~~, e.g.,~~ selected from group hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HC) or hydroxypropyl methyl cellulose (HPmC), acrylic acid polymers or a member of the poloxamer family.

8~~13~~.- The gel in accordance with claim 7~~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.~~

9.- A pharmaceutical formulation characterized in that it comprises a nano emulsion of 18β-glycyrrhetinic acid in a concentration of 0.01% to 30% by weight, wherein the formulation comprises additionally 2-(2-ethoxyethoxy)-ethanol from 40% to 71%;

at least a stabilizer selected of:

a polyoxyglyceride of capric, lauric, linoleic, oleic acid, or stearic acid triglycerides;

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;

castor oil or hydrogenated castor oil;

an emollient oleaginous vehicle; and

distilled water.

10.- The formulation in accordance with claim 9, characterized in that the percentages by weight of its components are: 0.01% to 30% of 18β-glycyrrhetinic acid; 40% to 60% for 2-(2-ethoxyethoxy)-ethanol; 10% to 20% for emollient oleaginous vehicle; 0% to 20% for castor oil or hydrogenated castor oil; 0% to 15% for ethoxylated fatty alcohol; and 5% to 50% for distilled water, wherein the emollient oleaginous vehicle is isopropyl myristate.

11~~5~~.- A method for preparing the formulation according to claim 9~~8~~, the method is characterized in that it comprises mixing the components described, in percentage by weight of the components: 0.~~0~~01% to 30% of 18β-glycyrrhetinic acid; 40% to 60% for 2-(2-ethoxyethoxy)-ethanol ~~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~~hydrogenated castor oil; 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~~ the 2-(2-ethoxyethoxy)-ethanol, with the emollient oleaginous vehicle;adding the castor oil or hydrogenated castor oil 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 dissolution~~ved~~, adding distilled water, stopping stirring and allowing to cool to room temperature.

12~~6~~.- The formulation according to claim 9~~8~~, characterized in that it has a particle size of 1 to 100 nm~~, or from 500 to 1000 nm~~.

13.- The formulation in accordance with claim 9, characterized in that it has a particle size of 500 to 1000 nm.

14~~7~~.- The formulation in accordance with~~ng to~~ claim ~~8~~9, 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.

15. - The formulation or gel in accordance with any one of the preceding claims for use in therapy.

16~~8~~.- ~~The~~Use of the formulation or gel according to any one of the preceding ~~ent~~ claims, in the manufacture of a medicament ~~to be~~for used in treating ~~the treatment of viral infections, wherein the use as an antiviral drug is for the treatment of~~ conditions caused by human papillomavirus viral infections, such as low-grade and high-grade intraepithelial lesions and cervical cancer.

17~~9~~. ~~The~~ Use of the formulation or gel according to any one of the preceding ~~ent~~ claims, in the manufacture of a medicament for ~~to be~~ used in ~~the~~ treating ~~ment of cancer, wherein the use as an anticancer agent is for the treatment of~~ cervical cancer.