CLAIMS

What is claimed is:

1. A topical pharmaceutical oil-in-water emulsion composition comprising:

about 0.1% to about 5% by weight of 3,5-dihydroxy-4-isopropyl-trans-stilbene or a pharmaceutically acceptable salt thereof,

mineral oil in an amount of about 5% to about 15% by weight, based on the total weight of the composition,

a co-solvent in an amount of about 1% to about 30% by weight, based on the total weight of the composition,

a water phase in an amount of 25% to about 85% by weight, based on the total weight of the composition,

a surfactant in an amount of about 0.1% to about 20% by weight, based on the total weight of the composition, comprising a mixture of polysorbate 80, nonionic emulsifying wax (Polawax NF), Steareth 2, and Steareth 20, and

an antioxidant.

2. The topical pharmaceutical oil-in-water emulsion composition of claim 1, further comprising an additional surfactant selected from the group consisting of non-ionic surfactants, ethoxylated fatty alcohol ethers, PEG castor oils, PEG esters, propylene glycol esters, glyceryl esters and derivatives, polymeric ethers, sorbitan derivatives, fatty alcohols, emulsifying waxes, and mixtures thereof.

3. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the co-solvent is selected from the group consisting of propylene glycol, di ethylene glycol monoethyl ether, transcutol, PEG 400, glycerine, ethanol, isopropanol, t-butyl alcohol, amyl alcohol, benzyl alcohol, cyclohexanedimethanol, diacetone alcohol, hexyl alcohol, tetrahydrofurfuryl alcohol, diethylene glycol monoethyl ether; carboxylic acids such as acetic acid or multi carboxylic acids; dials such as 1,2-hexanediol, butylene glycol, diethylene glycol, di propylene glycol, ethyl hexanediol, ethylene glycol, hexylene glycol, pentylene glycol, propylene glycol, tetraethylene glycol, triethylene glycol, tripropylene glycol and polyethylene glycol; polyols such as butanetriol, glycerol, 1,2,6-hexanetriol, macrogol-15-hydroxystearate, PEG 40, oleyl macrogol 6 glycerides, N-methyl-2-pyrrolidone, propylene glycol monolaurate, esters such as butyl stearate, Cl2-15 alkyl benzoate, Cl2-15

alkyl lactate, caprylic/capric triglyceride, cetearyl ethylhexanoate, cetearyl isononanoate, cetyl octanoate, cetyl palmitate, coco-caprylate/caprate, cocoglycerides, decyl oleate, dibutyl adipate, dicaprylyl carbonate, diethylhexyl adipate, di-ethylhexyl succinate, diisopropyl adipate, dioctyl malate, di-PPG-2 myreth-10 adipate, di-PPG-3 myristyl ether adipate, ethyl olcate, ethylhexyl cocoate, ethylhexyl hydroxystearate, ethylhexyl palmitate, ethylhexyl pelargonate, ethylhexyl stearate, hexyl laurate, hexyldecyl laurate, hexyldecyl stearate, isocetyl stearate, isocetyl stearoyl stearate, isodecyl oleate, isopropyl myristate, isopropyl palmitate, isostearyl neopentanoate, isotridecyl isononanoate, lauryl lactate, myristyl lactate, myristyl myristate, octyldodecyl stearoyl stearate, oleyl erucate, oleyl oleate, pentaerythrityl tetracaprylate/caprate, pentaerythrityl tetraisostearate, PPG-2 myristyl ether propionate, propylene glycol dicaprylate/ dicaprate, propylene glycol isostearate, propylheptyl caprylate, and stearyl octanoatedimethyl isosorbide, propylene carbonate, hydrogenated castor oil, PPG-15 stearyl ether, octyldodecanol, and combinations and mixtures thereof.

4. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein antioxidant is in an amount of about 0.001% to about 5%.

5. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the antioxidant is selected from the group consisting of butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), tocopherol, propyl gallate, vitamin E TPGS and tert-Butylhydroquinone (TBHQ), and mixtures thereof. In an embodiment, the antioxidant is selected from the group consisting of butylated hydroxytoluene, propyl gallate and tocopherol, and mixtures thereof.

6. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the pH of the composition is about 4 to about 7.

7. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the one or more additional dermatologically acceptable excipients is selected from the group consisting of pH adjusting agent, a chelating agent, a preservative, a co-solvent, a penetration enhancer, a humectant, a thickening agent, a gelling agent, a viscosity building agent, a fragrance, a colorant, and combinations thereof.

8. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the viscosity is about 10,000 mPa.s to about 300,000 mPa.s.

9. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the composition has a droplet size having a D90 of about 0.1 μm to about 35μm.

10. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the composition has a droplet size having a D50 of about 0.1 μm to about 35μm.

11. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the composition has an in vitro skin permeation profile of about 10 ng/cm^2 to about 65 ng/cm^2.

12. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the composition has an in vitro penetration into the epidermis profile of about 500 ng to about 5,200 ng.

13. The topical pharmaceutical oil-in-water emulsion composition of claim 1, wherein the composition has an in vitro penetration into the dermis profile of about 1,800 ng to about 12,000 ng.

14. ~~A method of treating a dermatological condition or disorder in a patient in need thereof, the method comprising administering to said patient~~Use of the topical pharmaceutical emulsion composition of any one of claims 1 to 13 in the manufacture of a medicament for treating a dermatological condition or disorder in a patient in need thereof, wherein the medicament is to be administered to said patient.

15. A topical pharmaceutical oil-in-water emulsion composition comprising:

about 0.1% to about 5% by weight of 3,5-dihydroxy-4-isopropyl-trans-stilbene or a pharmaceutically acceptable salt thereof,

an oil phase in an amount of about 5% to about 45% by weight, based on the total weight of the composition,

a water phase in an amount of about 25% to about 85% by weight, based on the total weight of the composition,

a surfactant in an amount of about 0.1% to about 20% by weight, based on the total weight of the composition,

an antioxidant, and

a co-solvent in an amount of greater than 30% by weight, based on the total weight of the composition.

16. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the surfactant is selected from the group consisting of non-ionic surfactants, ethoxylated fatty alcohol ethers, PEG castor oils, PEG esters, propylene glycol esters, glyceryl esters and derivatives, polymeric ethers, sorbitan derivatives, fatty alcohols, emulsifying waxes, and mixtures thereof.

17. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the oil phase is selected from the group consisting of fatty acids, esters, esters of glycerin, fatty alcohols, waxes, sterols, unsaponifiables, siloxanes, silanes, lanolin, hydrocarbons, essential oils, vegetable oils, mineral oils, animal oils, edible oils, and mixtures thereof

18. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the antioxidant is in an amount of about 0.001% to about 5%.

19. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the antioxidant is selected from the group consisting of butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), tocopherol, propyl gallate, vitamin E TPGS and tert-Butylhydroquinone (TBHQ), and mixtures thereof. In an embodiment, the antioxidant is selected from the group consisting of butylated hydroxytoluene, propyl gallate and tocopherol, and mixtures thereof.

20. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the pH of the composition is about 4 to about 7.

21. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the one or more additional dermatologically acceptable excipients is selected from the group consisting of pH adjusting agent, a chelating agent, a preservative, a co-solvent, a penetration enhancer, a humectant, a thickening agent, a gelling agent, a viscosity building agent, a fragrance, a colorant, and combinations thereof.

22. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the viscosity is about 10,000 mPa.s to about 300,000 mPa.s.

23. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the composition has a droplet size having a D90 of about 0.1 μm to about 35μm.

24. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the composition has a droplet size having a D50 of about 0.1 μm to about 35μm.

25. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the composition has an in vitro skin permeation profile of about 10 ng/cm^2 to about 65 ng/cm^2.

26. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the composition has an in vitro penetration into the epidermis profile of about 500 ng to about 5,200 ng.

27. The topical pharmaceutical oil-in-water emulsion composition of claim 15, wherein the composition has an in vitro penetration into the dermis profile of about 1,800 ng to about 12,000 ng.

28. ~~A method of treating a dermatological condition or disorder in a patient in need thereof, the method comprising administering to said patient~~ Use of the topical pharmaceutical emulsion composition of any one of claims 15 to 27 in the manufacture of a medicament for treating a dermatological condition or disorder in a patient in need thereof, wherein the medicament is to be administered to said patient.

29. A topical pharmaceutical oil-in-water emulsion composition comprising:

about 0.1% to about 5% by weight of 3,5-dihydroxy-4-isopropyl-trans-stilbene or a pharmaceutically acceptable salt thereof,

an oil phase in an amount of about 5% to about 35% by weight, based on the total weight of the composition and is selected from the group consisting of cocoyl caprylocaprate, isostearyl isostearate, octyldodecanol, jajoba oil, sesame oil, walnut oil, isopropyl palmitate, isopropyl myristate, safflower oil, mineral oil, olive oil, almond oil, and combinations thereof,

a water phase in an amount of about 25% to about 85% by weight, based on the total weight of the composition,

a surfactant in an amount of about 0.1% to about 20% by weight, based on the total weight of the composition, and

an antioxidant.

30. The topical pharmaceutical oil-in-water emulsion composition of claim 29 further comprising an oil phase selected from the group consisting of fatty acids, esters, esters of glycerin, fatty alcohols, waxes, sterols, unsaponifiables, siloxanes, silanes, lanolin, hydrocarbons, essential oils, vegetable oils, mineral oils, animal oils, edible oils, and mixtures thereof

31. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the surfactant is selected from the group consisting of non-ionic surfactants, ethoxylated fatty alcohol ethers, PEG castor oils, PEG esters, propylene glycol esters, glyceryl esters and derivatives, polymeric ethers, sorbitan derivatives, fatty alcohols, emulsifying waxes, and mixtures thereof.

32. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the antioxidant is in an amount of about 0.001% to about 5%.

33. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the antioxidant is selected from the group consisting of butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), tocopherol, propyl gallate, vitamin E TPGS and tert-Butylhydroquinone (TBHQ), and mixtures thereof. In an embodiment, the antioxidant is selected from the group consisting of butylated hydroxytoluene, propyl gallate and tocopherol, and mixtures thereof.

34. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the pH of the composition is about 4 to about 7.

35. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the one or more additional dermatologically acceptable excipients is selected from the group consisting of pH adjusting agent, a chelating agent, a preservative, a co-solvent, a penetration enhancer, a humectant, a thickening agent, a gelling agent, a viscosity building agent, a fragrance, a colorant, and combinations thereof.

36. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the viscosity is about 10,000 mPa.s to about 300,000 mPa.s.

37. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the composition has a droplet size having a D90 of about 0.1 μm to about 35μm.

38. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the composition has a droplet size having a D50 of about 0.1 μm to about 35μm.

39. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the composition has an in vitro skin permeation profile of about 10 ng/cm^2 to about 65 ng/cm^2.

40. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the composition has an in vitro penetration into the epidermis profile of about 500 ng to about 5,200 ng.

41. The topical pharmaceutical oil-in-water emulsion composition of claim 29, wherein the composition has an in vitro penetration into the dermis profile of about 1,800 ng to about 12,000 ng.

42. ~~A method of treating a dermatological condition or disorder in a patient in need thereof, the method comprising administering to said patient~~ Use of the topical pharmaceutical emulsion composition of any one of claims 29 to 41 in the manufacture of a medicament for treating a dermatological condition or disorder in a patient in need thereof, wherein the medicament is to be administered to said patient.

43. A topical pharmaceutical oil-in-water emulsion composition comprising:

about 0.1% to about 5% by weight of 3,5-dihydroxy-4-isopropyl-trans-stilbene or a pharmaceutically acceptable salt thereof,

an oil phase in an amount of about 5% to about 45% by weight, based on the total weight of the composition,

a water phase in an amount of about 25% to about 85% by weight, based on the total weight of the composition,

a surfactant in an amount of about 1% to about 20% by weight, based on the total weight of the composition and is selected from the group consisting of oleoyl polyoxyl-6 glycerides, PEG32 Stearate, PEG 75, PEG 20 cetostearyl ether, ceteareth-12, ceteareth-15, ethylene glycol palmitostearate, cetostearyl alcohol, glycerol monostearate, stearyl alcohol, cetyl alcohol, steareth-2, steareth-20, steareth-21, and combinations thereof, and

an antioxidant.

44. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the oil phase is selected from the group consisting of fatty acids, esters, esters of glycerin, fatty alcohols, waxes, sterols, unsaponifiables, siloxanes, silanes, lanolin, hydrocarbons, essential oils, vegetable oils, mineral oils, animal oils, edible oils, and mixtures thereof.

45. The topical pharmaceutical oil-in-water emulsion composition of claim 43, further comprising an additional surfactant selected from the group consisting of non-ionic surfactants, ethoxylated fatty alcohol ethers, PEG castor oils, PEG esters, propylene glycol esters, glyceryl esters and derivatives, polymeric ethers, sorbitan derivatives, fatty alcohols, emulsifying waxes, and mixtures thereof.

46. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the antioxidant is in an amount of about 0.001% to about 5%.

47. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the antioxidant is selected from the group consisting of butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), tocopherol, propyl gallate, vitamin E TPGS and tert-Butylhydroquinone (TBHQ), and mixtures thereof. In an embodiment, the antioxidant is selected from the group consisting of butylated hydroxytoluene, propyl gallate and tocopherol, and mixtures thereof.

48. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the pH of the composition is about 4 to about 7.

49. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the one or more additional dermatologically acceptable excipients is selected from the group consisting of pH adjusting agent, a chelating agent, a preservative, a co-

solvent, a penetration enhancer, a humectant, a thickening agent, a gelling agent, a viscosity building agent, a fragrance, a colorant, and combinations thereof.

50. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the viscosity is about 10,000 mPa.s to about 300,000 mPa.s.

51. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the composition has a droplet size having a D90 of about 0.1 μm to about 35μm.

52. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the composition has a droplet size having a D50 of about 0.1 μm to about 35μm.

53. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the composition has an in vitro skin permeation profile of about 10 ng/cm^2 to about 65 ng/cm^2.

54. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the composition has an in vitro penetration into the epidermis profile of about 500 ng to about 5,200 ng.

55. The topical pharmaceutical oil-in-water emulsion composition of claim 43, wherein the composition has an in vitro penetration into the dermis profile of about 1,800 ng to about 12,000 ng.

56. ~~A method of treating a dermatological condition or disorder in a patient in need thereof, the method comprising administering to said patient~~Use of the topical pharmaceutical emulsion composition of any one of claims 43 to 55 in the manufacture of a medicament for treating a dermatological condition or disorder in a patient in need thereof, wherein the medicament is to be administered said patient.

57. The topical pharmaceutical emulsion composition of any one of claims 1 to 13, 15 to 27, 29 to 41, 43 to 55 for use in therapy.