Claims

We claim:

1. A nanoparticle composition comprising a population of particles, wherein the majority of particles have diameters between approximately 10 and approximately 300 nanometers,

wherein the nanoparticle composition comprises at least one aqueous dispersion medium, at least one oil, and at least one surfactant,

wherein the oil is a medium chain triglyceride,

wherein the surfactant is a polysorbate, and

wherein the ratio of oil to surfactant is between about 0.5:1 to about 1:1.

2. The nanoparticle composition of claim 1, wherein the medium chain triglyceride is an acid containing 6–12 carbons atoms.

3. The nanoparticle composition of claim 1, wherein the medium chain triglyceride is 1349 oil.

4. The nanoparticle composition of claim 1, wherein the polysorbate is polysorbate 80.

5. The nanoparticle composition of claim 1, wherein the surfactant is super-refined polysorbate 80.

6. The nanoparticle composition of claim 1, further comprising a known therapeutic agent or independently active biologically active agent.

7. The nanoparticle composition of claim 6, wherein the known therapeutic agent or independently active biologically active agent is a protein.

8. The nanoparticle composition of claim 6, wherein the known therapeutic agent or independently active biologically active agent is an antibody.

9. The nanoparticle composition of claim 6, wherein the known therapeutic agent or independently active biologically active agent is a protein complex.

10. The nanoparticle composition of claim 6, wherein the known therapeutic agent or independently active biologically active agent is botulinum toxin.

11. The nanoparticle composition of claim 10, wherein the botulinum toxin is encapsulated within the particles.

12. The nanoparticle composition of claim 10, wherein the botulinum toxin is adsorbed on the surface of the particles.

13. The nanoparticle composition of claim 10, wherein the botulinum toxin is associated with the particle interface.

14. The nanoparticle composition of claim 10, wherein the botulinum toxin is selected from the group comprising type A, type Ab, type Af, type B, type Bf, type C1, type C2, type D, type E, type F, and type G.

15. The nanoparticle composition of claim 10, wherein the botulinum toxin is type A botulinum toxin.

16. The nanoparticle composition of claim 1, wherein the particles can penetrate skin without altering or changing the skin.

17. The nanoparticle composition of claim 1, wherein the particles can penetrate skin without the use of skin permeation enhancers or abrasives.

18. The nanoparticle composition of claim 1, wherein the particles can penetrate the top layer of skin without the use of skin permeation enhancers or abrasives.

19. The nanoparticle composition of claim 18, wherein the top layer of the skin is the surface of the stratum corneum.

20. The nanoparticle composition of claim 18, wherein the top layer of the skin includes dermal pores.

21. The nanoparticle composition of claim 18, wherein the top layer of the skin includes dermal glands.

22. The nanoparticle composition of any one of claims 1-21, wherein the nanoparticle composition does not contain parabens.

23. A lotion comprising methylparaben, mineral oil, isopropyl myristate, white petrolatum, emulsifying wax, and propylparaben.

24. The lotion of claim 23, further comprising Polysorbate 80, 1349 oil, or combination thereof.

25. The lotion of claim 23, wherein the lotion comprises two phases admixed with one another, wherein the first phase comprises methylparaben.

26. The lotion of claim 23, wherein the lotion comprises two phases admixed with one another, wherein the second phase comprises mineral oil, isopropyl myristate, white petrolatum, emulsifying wax, and propylparaben.

27. The lotion of claim 23, wherein the lotion comprises two phases admixed with one another, wherein the first phase comprises methylparaben and the second phase comprises mineral oil, isopropyl myristate, white petrolatum, emulsifying wax, and propylparaben.

28. A lotion comprising mineral oil, isopropyl myristate, white petrolatum, and emulsifying wax.

29. The lotion of claim 28, further comprising Polysorbate 80, 1349 oil, or combination thereof.

30. The lotion of claim 28, wherein the lotion comprises two phases admixed with one another, wherein the second phase comprises mineral oil, isopropyl myristate, white petrolatum, and emulsifying wax.

31. A pharmaceutical composition comprising the lotion of any one of claims 23-30 and a known therapeutic agent or independently active biologically active agent.

32. The pharmaceutical composition of claim 31, wherein the known therapeutic agent or independently active biologically active agent is a botulinum toxin, an antibody, or combination thereof.

33. A pharmaceutical composition comprising the nanoparticle composition of any one of claims 1-21 and a lotion.

34. A pharmaceutical composition comprising the nanoparticle composition of any one of claims 1-21 and the lotion of any one of claims 23-30.

35. The pharmaceutical composition of either of claims 31-34, wherein the pharmaceutical composition is formulated as a deodorant.

36. The pharmaceutical composition of either of claims 31-34, wherein the pharmaceutical composition is formulated as an antiperspirant.

37. A method comprising steps of:

providing a subject, and

administering the nanoparticle composition of any one of claims 1-21, the lotion of any one of claims 23-30, or the pharmaceutical composition of any one of claims 31-36 to the skin of the subject.

38. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of a condition or disorder associated with sebaceous glands.

39. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of a condition or disorder associated with sweat glands.

40. The method of claim 33, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of a condition or disorder associated with hair follicles.

41. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of the outer layer of the skin.

42. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of a condition or disorder selected from the group consisting of acne, hyperhidrosis, unwanted sweating, bromhidrosis, body odor, chromhidrosis, excess sebum-producing disorders, seborrhea, seborrheic dermatitis, rosacea, hair loss, psoriasis, dermal infections, viral infection, bacterial infection, fungal infection, actinic keratosis, eczematous dermatitis, atopic dermatitis, burns, Raynaud's phenomenon, lupus erthythematosus, hyperpigmentation disorders, melasma, hypopigmentation disorders, vitiligo, skin cancer, squamous cell skin carcinoma, basal cell skin carcinoma, arthritis, osteoarthritis, bruxism, cervical neck pain, dry eyes, gastrointestinal disorders, achalasia, esophageal spasm, gastroparesis, spasm of the sphincter of oddi, anal fissure, anismus, lateral epicondylitis, back pain, lower back pain, upper back pain, masseter muscle hypertrophy, facial nerve disorders, facial wrinkles, wrinkles involving the forehead, glabellar, rhytids and/or periorbital regions, unsightly facial expressions, neck lines, hyperfunctional facial lines, hyperkinetic facial lines, platysma bands, neuromuscular disorders and conditions involving muscular spasm or contracture, facial palsy such as hemi facial spasm, cerebral palsy, spasticisty due to stroke, blepharospasm, facial contracture, dystonia, cervical dystonia, laryngeal dystonia, oromandibular dystonia, writer's cramp, neuralgias, trigeminal neuralgia, neuropathic pain, Parkinson's disease, plantar fasciitis pain, prostate hyperplasia,

headache, migraine, essential headache, cervicogenic headache, tension headache, prostatic disorders, prostatic pain, prostatic hypertrophy, restless leg syndrome, rhinitis, allergic rhinitis, sialorrhea, skin pruritis, strabismus, temporomandibular joint ("TMJ") syndrome, tics, Tourette's syndrome, hemifacial spasm, tremor, essential tremor, urinary bladder dysfunction, detrusor sphincter dysnergia, painful bladder, bladder spasticity, overactive bladder, vaginismus, spasticity such as that resulting from multiple sclerosis, retroorbital muscle, various ophthalmologic conditions, and/or combinations thereof.

43. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of hyperhidrosis.

44. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of unwanted sweating.

45. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of bromhidrosis.

46. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of body odor.

47. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of chromhidrosis.

48. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of acne.

49. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of wrinkles.

50. The method of claim 37, wherein the nanoparticle composition, lotion, or pharmaceutical composition is administered for treatment of headache.

CLAIMS

1. A topical formulation comprising: a nanoparticle composition comprising a population of particles, wherein the majority of particles have diameters between approximately 10 and approximately 300 nanometers,

wherein the nanoparticle composition comprises at least one aqueous dispersion medium, at least one oil, and at least one surfactant,

wherein the oil is a medium chain triglyceride,

wherein the surfactant is a polysorbate, and

wherein the ratio of oil to surfactant is between about 0.5:1 to about 1:1; and,

wherein the topical formulation further comprises one or more excipients selected from the group consisting of: emulsifying wax, isopropyl myristate, mineral oil, white petrolatum, gelatin, methylparaben, propylparaben, or any combinations thereof.

2. The topical formulation of claim 1, wherein the topical formulation further comprises emulsifying wax, isopropyl myristate, mineral oil, white petrolatum and gelatin.

3. The topical formulation of claim 1, wherein the topical formulation does not contain parabens.

4. The topical formulation of claim 1, wherein the medium chain triglyceride is an acid containing 6-12 carbons atoms or is Labracfac Lipophile WL 1349 oil.

5. The topical formulation of claim 1, wherein the polysorbate is polysorbate 80.

6. The topical formulation of claim 1, further comprising a known therapeutic agent or independently active biologically active agent, optionally wherein the known therapeutic agent or independently active biologically active agent is a protein, a protein complex, an antibody or botulinum toxin.

7. The topical formulation of claim 6, wherein the known therapeutic agent or independently active biologically active agent is botulinum toxin the botulinum toxin is selected from the group comprising type A, type Ab, type Af, type B, type Bf, type C1, type C2, type D, type E, type F, and type G.

8. The topical formulation of any one of claims 1-7, wherein the topical formulation is a pharmaceutical formulation or cosmetic formulation.

9. The topical formulation of claim 8, wherein the particles can penetrate skin without altering or changing the structure of skin or without the use of skin permeation enhancers or abrasives.

10. The topical formulation of claim 7, wherein the particles can penetrate the top layer of skin without the use of skin permeation enhancers or abrasives.

11. The topical formulation of claim 10, wherein the top layer of the skin is characterized in that:

a) the top layer of the skin is the surface of the stratum corneum;

b) the top layer of the skin includes dermal pores;

c) the top layer of the skin includes dermal glands; or

any combination thereof.

12. The topical formulation of any one of claims 1-11, wherein the nanoparticles have a zeta potential ranging between -25 mV and +25 mV.

13. The topical formulation of any one of claims 6-12, wherein the known therapeutic agent or independently active biologically active agent remains stable for an extended period of time when stored at 2 °C to 8 °C.

14. The formulation of claim 7, formulated as

(i) a deodorant, an antiperspirant, a sunscreen, a shampoo, a conditioner, or any combination thereof, or

(ii) into a cream, a gel, a liniment, a lotion, an ointment, a powder, drops, an oil, a foam, a spray, a patch, a liquid or thickening lotion, or

(iii) as a cosmetic formulation selected from the group consisting of:

skin softeners, nutritional lotion type emulsions, cleansing lotions, cleansing creams, skin milks, emollient lotions, massage creams, emollient creams, make-up bases, lipsticks, facial packs, facial gels, shampoos, rinses, conditioners, body cleansers, hair-tonics, soaps, and any combination thereof.

15. Use of the topical formulation of any one of claims 1-14, in the manufacture of a medicament

(i) for treatment of

a) a condition or disorder associated with sebaceous glands;

b) a condition or disorder associated with sweat glands;

c) a condition or disorder associated with hair follicles;

d) the outer layer of skin; or

any combination thereof, or

(ii) for treatment of a condition or disorder selected from the group consisting of acne, hyperhidrosis, unwanted sweating, bromhidrosis, body odor, chromhidrosis, excess sebum-producing disorders, seborrhea, seborrheic dermatitis, rosacea, hair loss, psoriasis, dermal infections, viral infection, bacterial infection, fungal infection, actinic keratosis, eczematous dermatitis, atopic dermatitis, burns, Raynaud's phenomenon, lupus erthythematosus, hyperpigmentation disorders, melasma, hypopigmentation disorders, vitiligo, skin cancer, squamous cell skin carcinoma, basal cell skin carcinoma, arthritis, osteoarthritis, bruxism, cervical neck pain, dry eyes, gastrointestinal disorders, achalasia, esophageal spasm, gastroparesis, spasm of the sphincter of oddi, anal fissure, anismus, lateral epicondylitis, back pain, lower back pain, upper back pain, masseter muscle hypertrophy, facial nerve disorders, facial wrinkles, wrinkles involving the forehead, glabellar, rhytids and/or periorbital regions, unsightly facial expressions, neck lines, hyperfunctional facial lines, hyperkinetic facial lines,

platysma bands, neuromuscular disorders and conditions involving muscular spasm or contracture, facial palsy such as hemi facial spasm, cerebral palsy, spasticisty due to stroke, blepharospasm, facial contracture, dystonia, cervical dystonia, laryngeal dystonia, oromandibular dystonia, writer's cramp, neuralgias, trigeminal neuralgia, neuropathic pain, Parkinson's disease, plantar fasciitis pain, prostate hyperplasia, headache, migraine, essential headache, cervicogenic headache, tension headache, prostatic disorders, prostatic pain, prostatic hypertrophy, restless leg syndrome, rhinitis, allergic rhinitis, sialorrhea, skin pruritis, strabismus, temporomandibular joint ("TMJ") syndrome, tics, Tourette's syndrome, hemifacial spasm, tremor, essential tremor, urinary bladder dysfunction, detrusor sphincter dysnergia, painful bladder, bladder spasticity, overactive bladder, vaginismus, spasticity such as that resulting from multiple sclerosis, retroorbital muscle, various ophthalmologic conditions, and/or combinations thereof, wherein said medicament is to be administered to the skin of a subject.

16. A method for manufacturing a topical formulation, the method comprising steps of:

i) providing:

(a) a premix comprising: an aqueous dispersion medium, an oil, surfactant and optionally a known therapeutic or independently active agent;

(b) a cream or lotion formulation comprising one or more excipients selected from the group consisting of: mineral oil, isopropyl myristate, white petrolatum, emulsifying wax, methyparaben and propylparaben; and,

(c) providing a saline solution;

ii) combining the (a), (b) and (c) to generate the topical formulation of any one of claims 1-14, optionally wherein the premix (a) further comprises propylparaben, methylparaben or combination thereof, and/or wherein the cream or lotion formulation (b) comprises two phases admixed with one another, wherein the first phase comprises methylparaben, optionally wherein the second phase comprises mineral oil, isopropyl myristate, white petrolatum, emulsifying wax, and propylparaben, and/or wherein the saline solution further comprises a paraben.