Claims

What is claimed is:

1. An oral pharmaceutical composition comprising testosterone undecanoate solubilized in a carrier comprising at least one lipophilic surfactant and at least one hydrophilic surfactant in a total lipophilic surfactant to total hydrophilic surfactant ratio (w/w) falling in the range of about 6:1 to 3.5:1, wherein said solubilized testosterone undecanoate comprises 18 to 22 percent by weight of the composition.

2. The oral pharmaceutical composition of claim 1 in which the at least one hydrophilic surfactant comprises Cremophor RH 40 (polyoxyethyleneglycerol trihydroxystearate).

3. The oral pharmaceutical composition of claim 1 in which the at least one lipophilic surfactant comprises oleic acid.

4. The oral pharmaceutical composition of claim 1 in which the testosterone undecanoate is solubilized in a carrier free of ethanol.

5. The oral pharmaceutical composition of claim 2 in which comprises 15 to 17 percent by weight of the at least one hydrophilic surfactant.

6. The oral pharmaceutical composition of claim 1 which comprises 50 to 55 percent by weight of the at least one lipophilic surfactant

7. A pharmaceutical composition comprising testosterone undecanoate solubilized in a carrier comprising at least one lipophilic surfactant and at least one hydrophilic surfactant in a total lipophilic surfactant to total hydrophilic surfactant ratio (w/w) falling in the range of about 6:1 to 3.5:1, wherein said solubilized testosterone undecanoate comprises 18 to 22 percent by weight of the composition, the composition for used in a method of treating testosterone deficiency or its symptoms comprising orally administering to a subject suffering from testosterone deficiency or its symptoms an effective amount of the pharmaceutical composition.

8. The pharmaceutical composition for use in the method of claim 7 in which the composition is administered once daily.

9. The pharmaceutical composition for use in the method of claim 7 in which the composition is administered twice daily.

10. An oral pharmaceutical composition comprising:

    a. 18-22 percent by weight of solubilized testosterone undecanoate;
    b. 50-55 percent by weight of at least one lipophilic surfactant;
    c. 15-17 percent by weight of at least one hydrophilic surfactant; and
    d. 10-15 percent by weight of a mixture of borage seed oil and peppermint oil.

11. The composition as recited in claim 10 wherein said hydrophilic surfactant is Cremophor RH 40.

12. The composition as recited in claim 10 wherein said lipophilic surfactant is oleic acid.

13. The oral pharmaceutical composition as recited in claim 10 comprising:
    a. 19.8 percent by weight of solubilized testosterone undecanoate;
    b. 51.6 percent by weight of oleic acid;
    c. 16.1 percent by weight of Cremophor RH 40;;
    d. 10 percent by weight of borage seed oil;
    e. 2.5 percent by weight of peppermint oil; and
    f. 0.03 percent by weight of beta-hydroxy-toluene (BHT).

14. The composition as recited in Claim 10, wherein the ratio of lipophilic surfactant to hydrophilic surfactants is about 4:1.

Claims

1. An oral pharmaceutical composition comprising testosterone undecanoate solubilized in a carrier comprising at least one lipophilic surfactant and at least one hydrophilic surfactant in a total lipohilic surfactant to total hydrophilic surfactant ratio (w/w) falling in the range of about 6:1 to 3.5:1, wherein said solubilized testosterone undecanoate comprises 18 to 22 percent by weight of the composition, which composition upon once or twice daily oral administration, provides an average serum testosterone concentration at a steady state falling in the range of about 300 to about 1100 ng/dL.

2. The oral pharmaceutical composition of claim 1 in which the at least one hydrophilic surfactant comprises Cremophor RH 40 (polyoxyethyleneglycerol trihydroxystearate).

3. The oral pharmaceutical composition of claim 1 in which the at least one lipophilic surfactant comprises oleic acid.

4. The oral pharmaceutical composition of claim 1 in which the testosterone undecanoate is solubilized in a carrier substantially free of ethanol.

5. The oral pharmaceutical composition of claim 1 which comprises 15 to 17 percent by weight of the at least one hydrophilic surfactant.

6. The oral pharmaceutical composition of claim 1 which comprises 50 to 55 percent by weight of the at least one lipophilic surfactant.

7. A pharmaceutical composition comprising testosterone undecanoate solubilized in a carrier comprising at least one lipophilic surfactant and at least one hydrophilic surfactant in a total lipophilic surfactant to total hydrophilic surfactant ratio (w/w) falling in the range of about 6:1 to 3.5:1 to provide an average serum testosterone concentration at steady state falling in the range of about 300 to about 1100 ng/dL, wherein said solubilized testosterone undecanoate comprises 18 to 22 percent by weight of the composition, the composition for use in a method of treating testosterone deficiency or its symptoms comprising orally administering to a subject suffering from testosterone deficiency or its symptoms an effective amount of the pharmaceutical composition.

8. The pharmaceutical composition for use in the method of claim 7 in which the composition is administered once daily.

9. The pharmaceutical composition for use in the method of claim 7 in which the composition is administered twice daily.

10. An oral pharmaceutical composition comprising:

a. 18-22 percent by weight of solubilized testosterone undecanoate;

b. 50-55 percent by weight of at least one lipophilic surfactant; and;

c. 15-17 percent by weight of at least one hydrophilic surfactant;

d. 10-15 percent by weight of a mixture of borage seed oil and peppermint oil.

11. The composition as recited in claim 10 wherein said hydrophilic surfactant is Cremophor RH 40.

12. The composition as recited in claim 10 wherein said lipophilic surfactant is oleic acid.

13. The oral pharmaceutical composition as recited in claim 10 comprising:

a. 19.8 percent by weight of solubilized testosterone undecanoate;

b. 51.6 percent by weight of oleic acid;

c. 16.1 percent by weight of Cremophor RH 40;

d. 10 percent by weight of borage seed oil;

e. 2.5 percent by weight of peppermint oil; and

f. 0.03 percent by weight of BHT.

14. The composition as recited in Claim 10, wherein the ratio of lipophilic surfactants to hydrophilic surfactants is about 4:1.