We claim:

1. An oral pharmaceutical composition comprising testosterone undecanote 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, which composition, upon once- or twice-daily oral administration, provides an average serum testosterone concentration at steady state falling in the range of about 300 to about 1100 ng/dL.

2. The pharmaceutical composition of claim 1, which provides a C_{max} that does not exceed 2500 ng/dL when administered with a meal.

3. The pharmaceutical composition of claim 1, which provides a C_{max} that does not exceed 1800 ng/dL when administered with a meal.

4. The pharmaceutical composition of claim 1, which provides a C_{max} that does not exceed 1500 ng/dL when administered with a meal.

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

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

7. The oral pharmaceutical composition of claim 1 comprising 18 to 22 percent by weight of a solubilized testosterone undecanoate.

8. The oral pharmaceutical composition of claim 7 in which the testosterone undecanote is solubilized in a carrier substantially free of ethanol.

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

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

11. A dosage form of testosterone undecanoate comprising testosterone undecanote solubilized in a carrier comprising at least one lipophilic surfactant and at least one hydrophilic surfactant, which dosage form, upon once- or twice-daily oral administration to a subject suffering from hypogonadism or its symptons, provides an average serum testosterone concentration at steady state falling in the range of about 300 to about 1100 ng/dL, while avoiding an occurrence of a C_{max} value that exceeds 2500 ng/dL.

12. The dosage form of claim 11 which avoids an occurrence of a C_{max} value that exceeds 1800 ng/dL.

13. The dosage form of claim 11 which avoids an occurrence of a C_{max} value that exceeds 1500 ng/dL.

14. A pharmaceutical composition comprising testosterone undecanoate solubilized in a carrier comprising at least one lipophilic surfactant and at least one hydrophilic surfactant, which composition, upon oral administration with a meal having a fat content ranging from as low as 20 wt% to as high as 50 wt%, provides an average serum testosterone concentration that is statistically insignificant to that observed upon oral administration with a meal having a fat content of about 30 wt%.

15. A pharmaceutical composition comprising testosterone undecanote 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, which composition, upon once- or twice-daily oral administration, provides a serum testosterone rapid phase half-life of about 5 hours and a serum testosterone terminal high-life of about 29 hours.

16. A pharmaceutical composition comprising testosterone undecanote 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, which composition, upon once- or twice-daily oral administration to a subject suffering from testosterone deficiency

or its symptoms, provides a mean serum testosterone concentration at day 30 of a daily treatment regimen, which is substantially the same as that observed on day 7.

17. The pharmaceutical composition of claim 16 in which the mean serum testosterone concentration obtained at day 30 of a daily treatment regimen is substantially the same as that observed on day 60.

18. 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 a pharmaceutical composition comprising testosterone undecanote 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.

19. The method of claim 18 in which the composition is administered once daily.

20. The method of claim 18 in which the composition is administered twice daily.

21. The method of claim 18 which gives rise to a C_{max} value falling in the range of about 900 to 1100 ng/dL.

22. The method of claim 18 in which the composition is administered with a meal comprising at least 20 wt% fat.

23. The method of claim 18 which gives rise to substantially no diurnal testosterone pharmacokinetic variation.

24. The method of claim 18 which gives rise to an average serum T_{max} value falling in the range of about 3 to 7 hours after oral administration.

25. The method of claim 24 in which the average serum T_{max} value falls in the range of about 4 to 5 hours after oral administration.

26. The method of claim 18 in which substantially no significant decline in steady state serum testosterone response is observed upon repeat dosing.

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.