WHAT IS CLAIMED IS:

1. A controlled release formulation, comprising:

(a) a therapeutically effective amount of carvedilol free base or carvedilol salt thereof;

(b) a matrix forming polymer comprising one or more of the following: about 20% to about 60% by weight of Methocel K15M, about 15% to about 20% by weight of Methocel K100M, about 25% to about 35% by weight of Methocel E4M, about 35% to about 45% by weight of Eudragit RSPO, or about 35% to about 55% by weight of WSR N12NF;

(c) a solubility enhancer comprising one or more of the following: about 25% to about 55% by weight of Povidone, about 25% to about 35% by weight of PEG6000, or about 35% to about 45% by weight of HPC-L; and

(d) an excipient comprising one or more of the following: about 15% to about 35% by weight of corn starch, or about 0.1% to about 2% by weight of magnesium stearate.

2. The controlled release formulation of claim 1 wherein the carvedilol is carvedilol free base.

3. A controlled release formulation comprising, two or more subunits wherein at least one of said subunits is an immediate release carvedilol subunit comprising a therapeutically effective amount of carvedilol free base or carvedilol salt thereof, a matrix forming polymer, a solubility enhancer and a pharmaceutically acceptable carrier, and wherein at least one of said subunits is a slow release carvedilol subunit comprising a therapeutically effective amount of carvedilol free base or carvedilol salt thereof, a matrix forming polymer and a pharmaceutically acceptable carrier.

4. The controlled release formulation of claim 3 wherein the carvedilol is carvedilol free base.

5. The controlled release formulation according to claim 3, wherein the matrix forming polymer comprises one or more of the following: hydroxypropyl methylcellulose (HPMC), polyoxethylene oxide, alginate, methylcellulose, ethycellulose, methacrylic copolymer, or hydroethylmethylcellulose (HEMC).

6. The controlled release formulation according to claim 3, wherein the solubility enhancer comprises one or more of the following: hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HEC), polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), or sodium lauryl sulfate (SLS).

7. The controlled release formulation of Claim 5, wherein ethycellulose contains about 20% to about 80% (w/w) of ethoxyl.

8. The controlled release formulation of Claim 5, wherein the methoxyl content of the

hydroethylmethylcelluose (HEMC) is from about 10% to about 60% (w/w).

9. The controlled release formulation according to claim 3, wherein the pharmaceutically acceptable carrier comprises one or more of the following: lactose, corn starch or magnesium stearate.

10. The controlled release formulation according to claim 3,

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed $AUC_{0-\infty}$ of the controlled release formulation to a geometric mean of logarithmic transformed $AUC_{0-\infty}$ of the reference drug (Coreg CR™) of about 0.80 to about 1.20;

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed AUC_{0-t} of the controlled release formulation to a geometric mean of logarithmic transformed AUC_{0-t} of the reference drug (Coreg CR™) of about 0.80 to about 1.20; or

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed C_{max} of the controlled release formulation to a geometric mean of logarithmic transformed C_{max} of the reference drug (Coreg CR™) of about 0.80 to about 1.20.

11. The controlled release formulation according to claim 3, wherein the controlled release formulation exhibits a first peak plasma T_{max1} of about 4 hours, and a second peak plasma T_{max2} of about 24 hours after oral administration to a patient.

12. A controlled release formulation, comprising:

A. One or more immediate release subunits, comprising;

(i) a therapeutically effective amount of carvedilol free base or carvedilol salt thereof;

(ii) about 4% to about 5 % by weight of a matrix forming polymer comprising one or more of the following: hydroxypropyl methylcellulose (HPMC), polyoxethylene oxide, alginate, methylcellulose, ethycellulose, a methacrylic copolymer, or hydroethylmethylcellulose (HEMC); and

(iii) about 0.01% to about 0.1% by weight of an excipient; and

B. one or more slow release subunits, comprising;

(i) a therapeutically effective amount of carvedilol free base or carvedilol salt thereof;

(ii) about 20% to about 55 % by weight of a matrix forming polymer comprising one or more

of the following: hydroxypropyl methylcellulose (HPMC), polyoxethylene oxide, alginate, methylcellulose, ethycellulose, a methacrylic copolymer, or hydroethylmethylcellulose (HEMC);

(iii) about 1.0% to about 30 % by weight of a solubility enhancer comprising one or more of the following: hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HEC), polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), or sodium lauryl sulfate (SLS); and

(iv) about 0.01% to about 25 % by weight of an excipient.

13. The controlled release formulation according to claim 12, wherein carvedilol is carvedilol free base.

14. The controlled release formulation of Claim 12, wherein ethycellulose contains about 20% to about 80% (w/w) of ethoxyl.

15. The controlled release formulation of Claim 12, wherein the methoxyl content of the hydroethylmethylcelluose (HEMC) is from about 10% to about 60% (w/w).

16. The controlled release formulation according to claim 12, wherein the excipient comprises one or more of the following: lactose, corn starch, or magnesium stearate.

17. The controlled release formulation according to claim 12,

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed $AUC_{0-\infty}$ of the controlled release formulation to a geometric mean of logarithmic transformed $AUC_{0-\infty}$ of the reference drug (Coreg CR™) of about 0.80 to about 1.20;

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed AUC_{0-t} of the controlled release formulation to a geometric mean of logarithmic transformed AUC_{0-t} of the reference drug (Coreg CR™) of about 0.80 to about 1.20; or

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed C_{max} of the controlled release formulation to a geometric mean of logarithmic transformed C_{max} of the reference drug (Coreg CR™) of about 0.80 to about 1.20.

18. The controlled release formulation according to claim 12, wherein the controlled release formulation exhibits a first peak plasma T_{max1} of about 4 hours, and a second peak plasma T_{max2} of about 24 hours after oral administration to a patient.

19. A method of making a controlled release formulation, comprising:

A. Making an immediate release subunit, comprising the steps of:

i. Mixing and blending a therapeutically effective amount of carvedilol, about 4% to about 5 % by weight of a matrix-forming polymer to form a first mixture;

ii. Granulating said first mixture into first granules; and

B. Making a slow release subunit, comprising the steps of:

i. Mixing and blending a therapeutically effective amount of carvedilol, about 20% to about 55 % by weight of a matrix-forming polymer to form a mixture;

ii. Adding about 1.0% to about 30 % by weight of a solubility enhancer to said mixture to form a second mixture;

iii. Granulating said second mixture into said second granules; and

C. Adding about 0.01% to about 25% by weight of an excipient to said first and second granules, and compressing said first and second granules into a tablet.

20. The method according to Claim 19, wherein the step of granulating said first mixture further comprises heating said first mixture at a temperature about 50°C to about 70°C.

21. The method according to Claim 20, wherein the step of granulating said first mixture further comprises sieving said first mixture through a 20 mesh sieve.

22. The method according to Claim 19, wherein the step of granulating said second mixture comprises heating said second mixture at a temperature about 50°C to about 70°C.

23. The method according to Claim 22, wherein the step of granulating said second mixture further comprises sieving said second mixture through a 20 mesh sieve.

WHAT IS CLAIMED IS:

1. A controlled release formulation comprising, two or more subunits wherein at least one of said subunits is an immediate release carvedilol subunit comprising a therapeutically effective amount of carvedilol free base or carvedilol salt thereof, a matrix forming polymer, and a pharmaceutically acceptable carrier, and wherein at least one of said subunits is a slow release carvedilol subunit comprising a therapeutically effective amount of carvedilol free base or carvedilol salt thereof, a matrix forming polymer, a solubility enhancer and a pharmaceutically acceptable carrier, wherein the matrix forming polymer comprises ethycellulose having an ethoxyl content of about 20% to about 80% (w/w), or the matrix forming polymer comprises hydroethylmethylcelluose (HEMC) having a methoxyl content of from about 10% to about 60% (w/w).

2. The controlled release formulation of claim 1 wherein the carvedilol is carvedilol free base.

3. The controlled release formulation according to claim 1, wherein the solubility enhancer comprises one or more of the following: hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HEC), polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), or sodium lauryl sulfate (SLS).

4. The controlled release formulation according to claim 1, wherein the pharmaceutically acceptable carrier comprises one or more of the following: lactose, corn starch or magnesium stearate.

5. The controlled release formulation according to claim 1,

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed $AUC_{0-\infty}$ of the controlled release formulation to a geometric mean of logarithmic transformed $AUC_{0-\infty}$ of a reference drug (Coreg CR™) of about 0.80 to about 1.20;

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed AUC_{0-t} of the controlled release formulation to a geometric mean of logarithmic transformed AUC_{0-t} of a reference drug (Coreg CR™) of about 0.80 to about

1.20; or

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed C_{max} of the controlled release formulation to a geometric mean of logarithmic transformed C_{max} of a reference drug (Coreg CR™) of about 0.80 to about 1.20.

6. The controlled release formulation according to claim 1, wherein the controlled release formulation exhibits a first peak plasma T_{max1} of about 4 hours, and a second peak plasma T_{max2} of about 24 hours after oral administration to a patient.

7. A controlled release formulation, comprising:

A. One or more immediate release subunits, comprising;

(i) a therapeutically effective amount of carvedilol free base or carvedilol salt thereof;

(ii) about 4% to about 5 % by weight of a matrix forming polymer comprising one or more of the following: hydroxypropyl methylcellulose (HPMC), polyethylene oxide, alginate, methylcellulose, ethycellulose, a methacrylic copolymer, or hydroethylmethylcellulose (HEMC); and

(iii) about 0.01% to about 0.1% by weight of an excipient; and

B. one or more slow release subunits, comprising;

(i) a therapeutically effective amount of carvedilol free base or carvedilol salt thereof;

(ii) about 20% to about 55 % by weight of a matrix forming polymer comprising one or more of the following: hydroxypropyl methylcellulose (HPMC), polyethylene oxide, alginate, methylcellulose, ethycellulose, a methacrylic copolymer, or hydroethylmethylcellulose (HEMC);

(iii) about 1.0% to about 30 % by weight of a solubility enhancer comprising one or more of the following: hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HEC), polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), or sodium lauryl sulfate (SLS); and

(iv) about 0.01% to about 25 % by weight of an excipient.

8. The controlled release formulation according to claim 7, wherein carvedilol is carvedilol free base.

9. The controlled release formulation of Claim 7, wherein ethycellulose contains about 20% to about 80% (w/w) of ethoxyl.

10. The controlled release formulation of Claim 7, wherein the methoxyl content of the hydroethylmethylcelluose (HEMC) is from about 10% to about 60% (w/w).

11. The controlled release formulation according to claim 7, wherein the excipient comprises one or more of the following: lactose, corn starch, or magnesium stearate.

12. The controlled release formulation according to claim 7,

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed $AUC_{0-\infty}$ of the controlled release formulation to a geometric mean of logarithmic transformed $AUC_{0-\infty}$ of a reference drug (Coreg CR^{TM}) of about 0.80 to about 1.20;

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed AUC_{0-t} of the controlled release formulation to a geometric mean of logarithmic transformed AUC_{0-t} of a reference drug (Coreg CR^{TM}) of about 0.80 to about 1.20; or

wherein the controlled release formulation exhibits a ratio of a geometric mean of logarithmic transformed C_{max} of the controlled release formulation to a geometric mean of logarithmic transformed C_{max} of a reference drug (Coreg CR^{TM}) of about 0.80 to about 1.20.

13. The controlled release formulation according to claim 7, wherein the controlled release formulation exhibits a first peak plasma T_{max1} of about 4 hours, and a second peak plasma T_{max2} of about 24 hours after oral administration to a patient.

14. A controlled release formulation, which is selected from the group consisting of:

(i) a formulation comprising

(a) an immediate release subunit, comprising 2.9% by weight of carvedilol free base or a pharmaceutically acceptable salt thereof, 4.8% by weight of HPMC K100LV, and 11.3% by

weight of lactose; and

(b) an slow release subunit, comprising 9.1% by weight of carvedilol free base or a pharmaceutically acceptable salt thereof, 22.8% by weight of HPMC K15M, 26.2% by weight of PVP, and 22.8% by weight of corn starch;

(ii) a formulation comprising

(a) an immediate release subunit, comprising 2.7% by weight of carvedilol free base or a pharmaceutically acceptable salt thereof, 4.5% by weight of HPMC K100LV, 10.6% by weight of lactose and 0.05% by weight of magnesium stearate; and

(b) an slow release subunit, comprising 8.6% by weight of carvedilol free base or a pharmaceutically acceptable salt thereof, 53.6% by weight of HPMC K15M , 1.8% by weight of SLS, and 17.9% by weight of corn starch; and

(iii) a formulation comprising

(a) an immediate release subunit, comprising 1.2% by weight of carvedilol free base or a pharmaceutically acceptable salt thereof, 4.2% by weight of HPMC K100LV, and 10.1% by weight of lactose; and

(b) an slow release subunit, comprising 8.6% by weight of carvedilol free base or a pharmaceutically acceptable salt thereof, 35.7% by weight of HPMC K15M, 21.3% by weight of PVP, and 18.6% by weight of corn starch.