Claims

1. A suspension for coating of a medical device selected from a catheter balloon, a balloon catheter, a stent, or a cannula, the suspension containing:
   a) at least one tri-*O*-acylglycerol selected from the group consisting of trioctanoylglycerol, trinonanoylglycerol, tridecanoylglycerol, and triundecanoylglycerol,
   b) at least one limus active agent in the form of microcrystals, and
   c) a solvent or a solvent mixture in which the at least one tri-*O*-acylglycerol dissolves and in which the microcrystals of the at least one limus active agent do not dissolve,

   wherein the solvent is a non-solvent having a dielectric constant ε_r at 20°C of ≤2.0 or the solvent mixture contains at least 50% by volume of a non-solvent having a dielectric constant ε_r at 20°C of ≤ 2.0 and at least one polar organic solvent;

   wherein the non-solvent is selected from hexane, cyclohexane, and heptane; and the polar organic solvent is selected from ethyl acetate, ethanol, isopropanol, and acetone.

2. The suspension according to claim 1, wherein the at least one limus active agent is selected from the group comprising or consisting of rapamycin, everolimus, zotarolimus, umirolimus, deforolimus, myolimus, novolimus, pimecrolimus, ridaforolimus, tacrolimus, and temsirolimus.

3. The suspension according to claim 1 or 2, wherein the at least one tri-*O*-acylglycerol and the limus active agent are present in a mass ratio of 10% - 30% tri-*O*-acylglycerol to 90% - 70% limus active agent.

4. The suspension according to any one of claims 1 to 3, wherein the at least one limus active agent is in the form of microcrystals having a crystal size in the range of 1 µm to 300 µm.

5. The suspension according to any one of claims 1 to 4, wherein at least 70% of the at least one limus active agent is in the form of microcrystals having a crystal size ranging from 10 µm to 50 µm.

6. The suspension according to any one of claims 1 to 5, wherein the at least one limus active agent has a crystallinity of at least 90% by weight.

7. The suspension according to any one of claims 1 to 6, wherein the solvent mixture is a mixture of at least one polar organic solvent having an n-octanol-water partition coefficient $\log K_{OW}$ of -0.5 to +1,5 and a dielectric constant ε_r at 20°C of 5.0 to 30, and at least one nonpolar organic solvent having a dielectric constant ε_r at 20°C of ≤ 3.0 and an n-octanol-water partition coefficient $\log K_{OW}$ of ≥ 3.0.

8. A method of preparing the suspension according to any one of claims 1 to 7 comprising the following steps:
   a) dissolving at least one tri-*O*-acylglycerol selected from the group consisting of trioctanoylglycerol, trinonanoylglycerol, tridecanoylglycerol, and triundecanoylglycerol in a solvent or a solvent mixture;
   b) preparing a suspension of at least one limus active agent in the form of microcrystals and the solution from step a),

   wherein the microcrystals of the at least one limus active agent do not dissolve in the solution of step a),

   wherein the solvent is a non-solvent having a dielectric constant ε_r at 20°C of ≤2.0 or the solvent mixture contains at least 50% by volume of a non-solvent having a dielectric constant ε_r at 20°C of ≤ 2.0 and at least one polar organic solvent,

   wherein the non-solvent is selected from hexane, cyclohexane, and heptane; and the polar organic solvent is selected from ethyl acetate, ethanol, isopropanol, and acetone.

9. The method according to claim 8, wherein the at least one limus active agent is selected from the group comprising or consisting of rapamycin, everolimus, zotarolimus, umirolimus, deforolimus, myolimus, novolimus, pimecrolimus, ridaforolimus, tacrolimus, and temsirolimus.

10. The method according to claim 8 or 9, wherein the at least one limus active agent is in the form of microcrystals having a crystal size in the range of 1 µm to 300 µm.

11. The method according to any one of claims 8 to 10, wherein at least 70% of the at least one limus active agent is in the form of microcrystals having a crystal size in the range of 10 µm to 50 µm.

12. The method according to any one of claims 8 to 11, wherein the at least one limus active agent has a crystallinity of at least 90% by weight.

13. The method according to any one of claims 8 to 12, wherein the solvent mixture is a mixture of at least one polar organic solvent having an n-octanol-water partition coefficient $\log K_{OW}$ of -0.5 to +1,5 and a dielectric constant ε_r at 20°C of 5.0 to 30, and at least one nonpolar organic solvent having a dielectric constant ε_r at 20°C of ≤ 3.0 and an n-octanol-water partition coefficient $\log K_{OW}$ of ≥ 3.0.

14. A method for coating of a medical device selected from a catheter balloon, a balloon catheter, a stent, or a cannula, comprising the following steps:
    a) providing the medical device with a medical device surface,
    b) providing a suspension containing at least one tri-*O*-acylglycerol selected from the group consisting of trioctanoylglycerol, trinonanoylglycerol, tridecanoylglycerol, and triundecanoylglycerol, at least one limus active agent in the form of microcrystals, and a solvent or a solvent mixture, in which the at least one tri-O-acylglycerol dissolves and in which the microcrystals of the at least one limus active agent do not dissolve,
    wherein the solvent is a non-solvent having a dielectric constant ε_r at 20°C of ≤ 2.0 or the solvent mixture contains at least 50% by volume of a non-solvent having a dielectric constant ε_r at 20°C of ≤ 2.0 and at least one polar organic solvent;
    wherein the non-solvent is selected from hexane, cyclohexane, and heptane; and the polar organic solvent is selected from ethyl acetate, ethanol, isopropanol, and acetone, and
    c) applying the coating suspension to the surface of the medical device by means of a syringe method, pipetting method, capillary method, fold spraying method, dipping method, spraying method, dragging method, thread dragging method, drop dragging method, or rolling method.

15. The method according to claim 14, further comprising the following step d) drying the coating.

16. A medical device selected from a catheter balloon, a balloon catheter, a stent, or a cannula coated with at least one tri-*O*-acylglycerol selected from the group consisting of trioctanoylglycerol, trinonanoylglycerol, tridecanoylglycerol, and

triundecanoylglycerol, and at least one limus active agent in the form of microcrystals,
wherein the at least one tri-*O*-acylglycerol and the at least one limus active agent are present in a mass ratio of 10 % – 30% tri-*O*-acylglycerol to 90 % – 70% limus active agent,
wherein the at least one limus active agent is in the form of microcrystals having a crystal size in the range of 1 µm to 300 µm,
wherein at least 90% of the at least one limus active agent is in the form of microcrystals having a crystal size of at least 10 µm.

17. The medical device of claim 16, wherein the limus active agent is selected from the group comprising or consisting of rapamycin, everolimus, biolimus A9, pimecrolimus, zotarolimus, tacrolimus, deforolimus, myolimus, novolimus, ridaforolimus, and temsirolimus.

18. The medical device according to claim 16 or 17, wherein at least 70% of the at least one limus active agent is in the form of microcrystals having a crystal size in the range of 10 µm to 50 µm.

19. The medical device according to any one of claims 16 to 18, wherein the at least one limus active agent has a crystallinity of at least 90% by weight.

20. The medical device according to any one of claims 16 to 19, wherein a biostable or biodegradable, bioactive or bioinert polymeric, metallic or ceramic layer is present beneath the layer of the at least one tri-*O*-acylglycerol and the at least one limus active agent.