CLAIMS

1. A solid pharmaceutical daptomycin composition comprising at least one excipient selected from glycine and/or a sugar, characterized in that an amount of the solid pharmaceutical daptomycin composition containing 500 mg of daptomycin dissolves in 10 mL of 0.9% aqueous sodium chloride in less than 2 minutes at 25 degrees C, the solid pharmaceutical daptomycin composition obtainable by:

   a. forming an aqueous daptomycin solution comprising 105 mg/mL (10.5% w/v) daptomycin at a pH of 6.5-7.5, and

   b. converting the aqueous daptomycin formulation to the solid pharmaceutical daptomycin preparation.

2. The solid pharmaceutical daptomycin composition of claim 1, wherein the aqueous daptomycin solution is formed by combining daptomycin at a concentration of 125 – 130 mg/mL with water and sodium hydroxide.

3. The solid pharmaceutical daptomycin composition of claim 2, wherein the sodium hydroxide is provided to the aqueous daptomycin solution as 3N NaOH.

4. The solid pharmaceutical daptomycin composition of claim 3, wherein the aqueous daptomycin solution is formed at a temperature of 2 - 10°C.

5. The solid pharmaceutical daptomycin composition of claim 1, wherein the aqueous daptomycin solution is converted to the solid pharmaceutical composition by lyophilization.

6. The solid pharmaceutical daptomycin composition of claim 4, wherein the aqueous daptomycin solution is converted to the solid pharmaceutical composition by lyophilization ~~according to the lyophilization cycle in Example 3~~.

7. The solid pharmaceutical daptomycin composition of claim 1, ~~further comprising~~wherein the at least one excipient is glycine.

8. The solid pharmaceutical daptomycin composition of claim 1, ~~further comprising~~ wherein the at least one excipient is a non-reducing sugar.

9. The solid pharmaceutical daptomycin composition of claim 1, ~~further comprising~~wherein the at least one excipient is sucrose.

10. The solid pharmaceutical daptomycin composition of claim 6, further comprising sucrose.

11. The solid pharmaceutical daptomycin composition of claim 9, wherein the aqueous daptomycin solution comprises 15% sucrose at a pH of 7.0.

12. A vial comprising the solid pharmaceutical daptomycin composition of any one of claims 1-11, the vial containing 500 mg of daptomycin.

13. The vial of claim 12 containing the solid pharmaceutical daptomycin composition dissolved in about 10 mL of 0.9% aqueous sodium chloride.

14. Use of the solid pharmaceutical daptomycin composition in any one of claims 1-11 in the manufacture of a medicament for the treatment of a bacterial infection.

15. The vial in any one of claims 12-13 for use in the treatment of a bacterial infection.

16. A solid pharmaceutical daptomycin composition characterized in that an amount of the solid pharmaceutical daptomycin composition containing 500 mg of daptomycin dissolves in 10 mL of 0.9% aqueous sodium chloride in less than 2 minutes at 25 degrees C, the solid pharmaceutical daptomycin composition obtainable by:

    a. forming an aqueous daptomycin solution comprising 105 mg/mL (10.5% w/v) daptomycin and 15% w/v sucrose at a pH of 7.0, and

    b. converting the aqueous daptomycin formulation to the solid pharmaceutical daptomycin preparation.

17. A solid pharmaceutical daptomycin composition characterized in that an amount of the solid pharmaceutical daptomycin composition containing 500 mg of daptomycin dissolves in 10 mL of 0.9% aqueous sodium chloride in less than 5 minutes at 25 degrees C, the solid pharmaceutical daptomycin composition obtainable by:

    a. forming an aqueous daptomycin solution comprising daptomycin and one or more sugars at a pH of 4.7, and

b. converting the aqueous daptomycin formulation to the solid pharmaceutical daptomycin preparation.

18. The solid pharmaceutical daptomycin composition of claim 17, wherein the aqueous daptomycin solution comprises 105 mg/mL (10.5% w/v) daptomycin and one or more sugars selected from the group consisting of: sucrose, trehalose, mannitol, lactose, maltose, dextrose, and fructose.

19. The solid pharmaceutical daptomycin composition of claim 18, further characterized in that an amount of the solid pharmaceutical daptomycin composition containing 500 mg of daptomycin dissolves in 10 mL of 0.9% aqueous sodium chloride in less than 2 minutes.

20. A method of manufacturing a solid pharmaceutical daptomycin composition characterized in that an amount of the solid pharmaceutical daptomycin composition containing 500 mg of daptomycin dissolves in 10 mL of 0.9% aqueous sodium chloride in less than 2 minutes at 25 degrees C, the method of manufacturing the solid pharmaceutical daptomycin composition comprising the steps of:

a. forming an aqueous daptomycin solution comprising 105 mg/mL (10.5% w/v) daptomycin and 15% w/v sucrose at a pH of 7.0, and

b. converting the aqueous daptomycin formulation to the solid pharmaceutical daptomycin preparation ~~according to the lyophilization cycle in Example 3~~.

21. A solid pharmaceutical daptomycin composition characterized in that an amount of the solid pharmaceutical daptomycin composition containing 500 mg of daptomycin dissolves in 10 mL of 0.9% aqueous sodium chloride in less than 5 minutes at about 25 degrees C, the solid pharmaceutical daptomycin composition comprising daptomycin and at least one excipient selected from glycine and a sugar.

22. The solid pharmaceutical daptomycin composition of claim 21, wherein the sugar is a non-reducing sugar.

23. The solid pharmaceutical daptomycin composition of claim 22, wherein the molar ratio of daptomycin to the sugar is about 1:1.12 to about 1:21.32.

24. The solid pharmaceutical daptomycin composition of claim 22 or 23, wherein the sugar is selected from trehalose, sucrose, and mannitol.

25. The solid pharmaceutical daptomycin composition of claim 21, wherein the solid pharmaceutical daptomycin composition comprises daptomycin and trehalose.

26. The solid pharmaceutical daptomycin composition of claim 25, wherein the molar ratio of daptomycin to trehalose is about 1:2.13 to about 1:21.32.

27. The solid pharmaceutical daptomycin composition of claim 21, wherein the solid pharmaceutical daptomycin composition comprises daptomycin and sucrose.

28. The solid pharmaceutical daptomycin composition of claim 27, wherein the molar ratio of daptomycin to sucrose is about 1:1.12 to about 1:8.98.

29. The solid pharmaceutical daptomycin composition of claim 21, wherein the solid pharmaceutical daptomycin composition comprises daptomycin and mannitol.

30. The solid pharmaceutical daptomycin composition of claim 29, wherein the molar ratio of daptomycin to mannitol is about 1:2.52 to about 1:5.04.

31. The solid pharmaceutical daptomycin composition of any one of claims 21-30, wherein the solid pharmaceutical daptomycin composition is obtainable by:

a. forming an aqueous daptomycin solution comprising daptomycin and said excipient at a pH of about 4.5-8.0, and

b. converting the aqueous daptomycin solution to the solid pharmaceutical daptomycin composition.

32. A solid pharmaceutical daptomycin composition characterized in that an amount of the solid pharmaceutical daptomycin composition containing 500 mg of daptomycin dissolves in 10 mL of 0.9% aqueous sodium chloride in less than 5 minutes at about 25 degrees C, wherein the solid pharmaceutical daptomycin composition is obtainable by:

a. forming an aqueous daptomycin solution comprising daptomycin at a pH of about 4.5-8.0, and

b. converting the aqueous daptomycin solution to the solid pharmaceutical daptomycin composition.

33. The solid pharmaceutical daptomycin composition of claim 31 wherein said Step a comprises forming an aqueous daptomycin solution at a pH of about 4.7-7.5.

34. The solid pharmaceutical daptomycin composition of claim 31 wherein said Step a comprises forming an aqueous daptomycin solution at a pH of about 5.0-7.5.

35. The solid pharmaceutical daptomycin composition of claim 32, wherein said Step a comprises forming an aqueous daptomycin solution at a pH of about 4.7-7.0.

36. The solid pharmaceutical daptomycin composition of claim 31 or 32, wherein said Step a comprises forming an aqueous daptomycin solution at a pH of about 6.5-7.5.

37. The solid pharmaceutical daptomycin composition of any one of claims 31-36, wherein the aqueous daptomycin solution further comprises a buffering agent.

38. The solid pharmaceutical daptomycin composition of any one of claims 31-37, wherein Step b comprises converting the aqueous daptomycin solution to a solid pharmaceutical composition by lyophilization, spray drying or fluid bed drying.

39. The solid pharmaceutical daptomycin composition of any one of claims 22-30, characterized in that an amount of the solid pharmaceutical daptomycin composition containing 500 mg of daptomycin dissolves in 10 mL of 0.9% aqueous sodium chloride in less than 2 minutes at about 25 degrees C.

40. A pharmaceutical product comprising the solid pharmaceutical daptomycin composition of any one of claims 21-39 and a pharmaceutically acceptable diluent.

41. Use of the solid pharmaceutical daptomycin composition in any one of claims 21-39 for the manufacture of a medicament for use in the treatment of a bacterial infection.

42. Use of the pharmaceutical product of claim 40 for the manufacture of a medicament for the treatment of a bacterial infection.

43. A method of manufacturing a solid pharmaceutical daptomycin composition, the method comprising:

a. forming an aqueous daptomycin solution comprising daptomycin and at least one excipient selected from glycine and a sugar at a pH of about 4.5-8.0, and

b. converting the aqueous daptomycin solution to the solid pharmaceutical daptomycin composition.

44. A method of manufacturing a solid pharmaceutical daptomycin composition, the method comprising:

a. forming an aqueous daptomycin solution comprising daptomycin at a pH of about 4.5-8.0, and

b. converting the aqueous daptomycin solution to the solid pharmaceutical daptomycin composition.

45. The method of claim 43, wherein said Step a comprises forming an aqueous daptomycin solution at a pH of about 4.7-7.5.

46. The method of claim 43, wherein said Step a comprises forming an aqueous daptomycin solution at a pH of about 5.0-7.5.

47. The method of claim 44, wherein said Step a comprises forming an aqueous daptomycin solution at a pH of about 4.7-7.0.

48. The method of claim 43 or 44, wherein said Step a comprises forming an aqueous daptomycin solution at a pH of about 6.5-7.5.