WE CLAIM:

1. A crystalline obeticholic acid Form C characterized by an X-ray diffraction pattern including characteristic peaks at about 4.2, 6.4, 9.5, 12.5, and 16.7 degrees 2-Theta.

2. A crystalline obeticholic acid Form C characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 5.

3. The crystalline obeticholic acid Form C according to claim 1 characterized by an X-ray diffraction pattern including characteristic peaks at about 4.2, 6.4, 9.5, 12.5, 12.6, 15.5, 15.8, 16.0, 16.7 and 19.0 degrees 2-Theta.

4. The crystalline obeticholic acid Form C according to claim 1 or claim 3 characterized by an X-ray diffraction pattern including characteristic peaks at about 4.2, 6.4, 8.3, 9.5, 11.1, 12.2, 12.5, 12.6, 15.5, 15.8, 16.0, 16.3, 16.7, 18.6 and 19.0 degrees 2-Theta.

5. The crystalline obeticholic acid Form C according to any one of claims 1 or 3-4 characterized by an X-ray diffraction pattern including characteristic peaks at about 4.2, 6.4, 8.3, 9.5, 11.1, 12.2, 12.5, 12.6, 15.5, 15.8, 16.0, 16.3, 16.7, 17.0, 17.8, 18.6, 18.8, 19.0, 20.5 and 20.9 degrees 2-Theta.

6. The crystalline obeticholic acid Form C according to any one of claims 1-5, wherein the X-ray diffraction pattern is collected on a diffractometer using Cu Kα radiation.

7. The crystalline obeticholic acid Form C according to any one of claims 1-6 characterized by an X-ray diffraction pattern including characteristic peaks at about 12.0 to about 12.8 and about 15.4 to about 21.0.

8. A crystalline obeticholic acid Form C characterized by a Differential Scanning Calorimetry (DSC) thermogram having an endotherm value at about 98±2 °C.

9. The crystalline obeticholic acid Form C according to any one of claims 1-8, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having an endotherm value at about 98±2 °C.

10. A process for preparing obeticholic acid Form 1, comprising a crystalline form of obeticholic acid as a synthetic intermediate.

11. A process for preparing obeticholic acid Form 1, comprising converting crystalline obeticholic acid to obeticholic acid Form 1.

12. The process according to claim 11, comprising the steps of

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

13. The process according to any one of claims 11-12, comprising the steps of

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

14. The process according to any one of claims 11-13, comprising the steps of

reacting 3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

15. The process according to any one of claims 11-14, comprising the steps of

reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form 3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

16. The process according to any one of claims 11-15, comprising the steps of

reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester with $Li[N(CH(CH_3)_2)_2]$ and $Si(CH_3)_3Cl$ to form 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester,

reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

17. The process according to any one of claims 11-16, comprising the steps of

reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid with CH_3OH and H_2SO_4 to form 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester,

reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester with $Li[N(CH(CH_3)_2)_2]$ and $Si(CH_3)_3Cl$ to form 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester,

reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

18. The process according to any one of claims 10-17, wherein the crystalline obeticholic acid is Form C.

19. The process according to claim 18, wherein crystalline obeticholic acid Form C is characterized by an X-ray diffraction pattern similar to that set forth in Figure 5.

20. The process according to any one of claims 18 or 19, wherein the crystalline obeticholic acid Form C is crystallized from n-butyl acetate.

21. The process according to any one of claims 11-17, wherein converting crystalline obeticholic acid Form C to obeticholic acid Form 1 comprises the step of dissolving crystalline obeticholic acid Form C in aqueous NaOH solution and adding HCl.

22. The process according to claim 21, wherein the isolated crystalline obeticholic acid Form C is dried under vacuum at about 80 °C.

23. The process according to any one of claims 12-17, wherein reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid is carried out at a temperature at about 85 °C to about 110 °C in a basic aqueous solution.

24. The process according to claim 23, wherein the temperature is about 90 °C to about 105 °C.

25. The process according to any one of claims 23-24, wherein the basic aqueous solution is an aqueous NaOH solution.

26. The process according to any one of claims 25, wherein the basic aqueous solution is a mixture of 50% wt. NaOH solution and water.

27. The process according to any one of claims 13-17, wherein reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid is carried out at a temperature at about 20 °C to about 40 °C and at a pressure at about 4 to about 5 bars.

28. The process according to claim 27, wherein, the organic phase of the reaction mixture is treated with activated carbon.

29. The process according to any one of claims 27-28, wherein the temperature is about 25 °C to about 35 °C.

30. The process according to any one of claims 27-29, wherein the pressure is about 4.5 to about 5.5 bars.

31. The process according to any one of claims 27-30, wherein the hydrogenation reaction mixture is allowed to stir for about 1 hour.

32. The process according to any one of claims 27-31, wherein reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas is heated to about 100 °C and stirred for about 2 hour to about 5 hours.

33. The process according to any one of claims 27-32, wherein reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas is heated to about 100 °C and stirred for about 3 hours.

34. The process according to any one of claims 14-17, wherein reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid is carried out at a temperature at about 20 °C to about 60 °C.

35. The process according to claim 34, wherein the temperature is about 20 °C to about 25 °C.

36. The process according to any one of claims 34-35, wherein reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH is carried out in methanol, water, and a NaOH solution.

37. The process according to any one of claims 34-36, wherein the NaOH solution is a 50% wt. aqueous solution.

38. The process according to any one of claims 15-17, wherein reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form E- or E/Z- 3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester is carried out in a polar aprotic solvent at a temperature at about -50 °C to about -70 °C in the presence of BF_3.

39. The process according to claim 38, wherein the polar aprotic solvent is dichloromethane.

40. The process according to any one of claims 38-39, wherein the BF_3 is a 16% wt. solution in acetonitrile.

41. The process according to any one of claims 38-40, wherein the temperature is about
-60 °C to about -65 °C.

42. The process according to any one of claims 16-17, wherein reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester with $Li[N(CH(CH_3)_2)_2]$ and $Si(CH_3)_3Cl$ to form 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester is carried out in a polar aprotic solvent at a temperature at about -10 °C to about -30 °C.

43. The process according to claim 42, wherein the polar aprotic solvent is tetrahydrofuran.

44. The process according to any one of claims 42-43, wherein the temperature is about
-20 °C to about -25 °C.

45. The process according to any one of claims 42-44, wherein reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester with $Li[N(CH(CH_3)_2)_2]$ and $Si(CH_3)_3Cl$ is stirred for about 2 hours.

46. The process according to claim 17, wherein reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid with CH_3OH and H_2SO_4 to form 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester is heated for about 3 hours and the pH of the reaction mixture is adjusted with an aqueous basic solution to a pH-value of about 6.5 to about 8.0.

47. The process according to claim 46, wherein the isolation of 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester further comprises the addition of activated carbon.

48. The process according to any one of claims 46-47, wherein reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid with CH_3OH and H_2SO_4 is carried out in methanol.

49. The process according to any one of claims 46-48, wherein the basic solution is an aqueous NaOH solution.

50. The process according to any one of claims 46-49, wherein the pH is about 7.0 to about 7.5.

51. A compound E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid produced by the process according to any one of claims 10-50, wherein the E/Z isomer ratio is greater than about 50%, greater than about 60%, greater than about 70%, greater than about 80%, greater than about 83%, greater than about 85%, greater than about 90%, greater than about 93%, greater than about 95 %, or greater than about 99%.

52. The compound according to claim 51, wherein the E/Z ratio is determined by HPLC.

53. The compound according to any one of claims 51-52, wherein the ratio is greater than about 80%.

54. The compound according to any one of claims 51-53, wherein the ratio is greater than about 83%.

55. The compound according to any one of claims 51-54, wherein the ratio is greater than about 85%.

56. The compound according to any one of claims 51-55, wherein the ratio is greater than about 90%.

57. The compound according to any one of claims 51-56, wherein the ratio is greater than about 93%.

58. The compound according to any one of claims 51-57, wherein the ratio is greater than about 95%.

59. The compound according to any one of claims 51-58, wherein the ratio is greater than about 99%.

~~60. A obeticholic acid, or a pharmaceutically acceptable salt, solvate or amino acid~~ conjugate thereof, having a potency of greater than about 98%.

61. The obeticholic acid of claim 60, wherein said obeticholic acid has a potency of greater than about 98%.

62. The obeticholic acid according to claim 60, wherein the potency of said obeticholic acid is determined by subtracting the amount of water, sulphated ash, residual solvents, and other organic impurities.

63. The obeticholic acid according to any one of claims 61-62 having a potency of greater than about 98.5%.

64. The obeticholic acid according to any one of claims 61-63 having a potency of greater than about 99.0%.

65. The obeticholic acid according to any one of claims 61-64 having a potency of greater than about 99.5%.

66. The obeticholic acid according to any one of claims 61-65, wherein said obeticholic acid contains a total of less than about 2% of one or more impurities selected from 6-ethylursodeoxycholic acid, 3α-hydroxy-6α-ethyl-7-cheto-5β-cholan-24-oic acid, 6β-ethylchenodeoxycholic acid, 3α,7α-dihydroxy-6-ethyliden-5β-cholan-24-oic acid, chenodeoxycholic acid, and 3α(3α,7α-dihydroxy-6α-ethyl-5β-cholan-24-oyloxy)-7α-hydroxy-6α-ethyl-5β-cholan-24-oic acid.

67. The obeticholic acid according to claim 66, wherein said obeticholic acid contains a total of less than about 1.5% of impurities.

68. The obeticholic acid according to any one of claims 66-67, wherein said obeticholic acid Form 1 contains a total of less than about 1.4% of impurities.

69. The obeticholic acid according to any one of claims 66-68, wherein said obeticholic acid contains less than about 1.2% of water.

70. The obeticholic acid according to any one of claims 66-69, wherein said obeticholic acid contains less than about 1.0% of water.

71. The obeticholic acid according to any one of claims 66-70, wherein said obeticholic acid contains a total of less than about 0.15% of 6-ethylursodeoxycholic acid and 3α,7α-dihydroxy-6-ethyliden-5β-cholan-24-oic acid.

72. The obeticholic acid according to any one of claims 66-71, wherein said obeticholic acid contains a total of less than about 0.06% of 6-ethylursodeoxycholic acid and 3α,7α-dihydroxy-6-ethyliden-5β-cholan-24-oic acid.

73. The obeticholic acid according to any one of claims 66-72, wherein said obeticholic acid contains a total of less than about 0.05% of 6-ethylursodeoxycholic acid and 3α,7α-dihydroxy-6-ethyliden-5β-cholan-24-oic acid.

74. The obeticholic acid according to any one of claims 66-73, wherein said obeticholic acid contains less than about 0.15% of 3α-hydroxy-6α-ethyl-7-cheto-5β-cholan-24-oic acid.

75. The obeticholic acid according to any one of claims 66-74, wherein said obeticholic acid contains less than about 0.06% of 3α-hydroxy-6α-ethyl-7-cheto-5β-cholan-24-oic acid.

76. The obeticholic acid according to any one of claims 66-75, wherein said obeticholic acid contains less than about 0.05% of 3α-hydroxy-6α-ethyl-7-cheto-5β-cholan-24-oic acid.

77. The obeticholic acid according to any one of claims 66-76, wherein said obeticholic acid contains less than about 0.15% of 6β-ethylchenodeoxycholic acid.

78. The obeticholic acid according to any one of claims 66-77, wherein said obeticholic acid contains less than about 0.06% of 6β-ethylchenodeoxycholic acid.

79. The obeticholic acid according to any one of claims 66-78, wherein said obeticholic acid contains less than about 0.05% of 6β-ethylchenodeoxycholic acid.

80. The obeticholic acid according to any one of claims 66-79, wherein said obeticholic acid contains less than about 3% of chenodeoxycholic acid.

81. The obeticholic acid according to any one of claims 66-80, wherein said obeticholic acid contains less than about 1% of chenodeoxycholic acid.

82. The obeticholic acid according to any one of claims 66-81, wherein said obeticholic acid contains less than about 0.2% of chenodeoxycholic acid.

83. The obeticholic acid according to any one of claims 66-82, wherein said obeticholic acid contains less than about 0.15% of 3α(3α,7α-dihydroxy-6α-ethyl-5β-cholan-24-oyloxy)-7α-hydroxy-6α-ethyl-5β-cholan-24-oic acid.

84. The obeticholic acid according to any one of claims 66-83, wherein said obeticholic acid contains less than about 0.06% of 3α(3α,7α-dihydroxy-6α-ethyl-5β-cholan-24-oyloxy)-7α-hydroxy-6α-ethyl-5β-cholan-24-oic acid.

85. The obeticholic acid according to any one of claims 66-84, wherein said obeticholic acid contains less than about 0.05% of 3α(3α,7α-dihydroxy-6α-ethyl-5β-cholan-24-oyloxy)-7α-hydroxy-6α-ethyl-5β-cholan-24-oic acid.

86. The obeticholic acid according to any one of claims 61-85, wherein the obeticholic acid is obeticholic acid Form 1.

87. A crystalline obeticholic acid, or a pharmaceutically acceptable salt, solvate or amino acid conjugate thereof, wherein said crystalline obeticholic acid is Form C.

88. The crystalline obeticholic acid according to claim 87, wherein said crystalline obeticholic acid has a potency greater than about 90%.

89. The crystalline obeticholic acid Form C according to claim 88, wherein the potency of said obeticholic acid Form C is determined by subtracting the amount of water, sulphated ash, residual solvents, and other organic impurities.

90. The crystalline obeticholic acid Form C according claim 87, wherein the solvate is a hydrate.

91. The crystalline obeticholic acid Form C according to any one of claims 88-90 having a potency of greater than about 92%.

92. The crystalline obeticholic acid Form C according to any one of claims 88-91 having a potency of greater than about 94%.

93. The crystalline obeticholic acid Form C according to any one of claims 88-92 having a potency of greater than about 96%.

94. The crystalline obeticholic acid Form C according to any one of claims 88-93 having a potency of greater than about 98%.

95. The crystalline obeticholic acid Form C according to any one of claims 88-94 having a potency of greater than about 99%.

96. The crystalline obeticholic acid Form C according to any one of claims 87-95, wherein the crystalline obeticholic acid Form C contains a total of less than about 4% of one or more impurities selected from 6-ethylursodeoxycholic acid, 3α-hydroxy-6α-ethyl-7-cheto-5β-cholan-24-oic acid, 6β-ethylchenodeoxycholic acid, 3α,7α-dihydroxy-6-ethyliden-5β-cholan-24-oic acid, chenodeoxycholic acid, and 3α(3α,7α-dihydroxy-6α-ethyl-5β-cholan-24-oyloxy)-7α-hydroxy-6α-ethyl-5β-cholan-24-oic acid.

97. The crystalline obeticholic acid Form C according to claim 96, wherein the total impurities is less than about 3.8 %.

98. The crystalline obeticholic acid Form C according to any one of claims 96-97, wherein the total impurities is less than about 3.6%.

99. A pharmaceutical composition comprising obeticholic acid Form 1 produced by the process of any one of claims 10-50 and a pharmaceutically acceptable carrier.

100. A pharmaceutical composition comprising of crystalline obeticholic acid and a pharmaceutically acceptable carrier.

101. The pharmaceutical composition according to claim 100, wherein the crystalline obeticholic acid is Form C.

102. A method of treating or preventing an FXR mediated disease or condition in a subject comprise of administering an effective amount of obeticholic acid Form 1 according to any one of claims 60-86 or produced by a process according to any one of claims 10-50, or a pharmaceutical composition according to claim 99.

103. A method of treating or preventing an FXR mediated disease or condition in a subject comprise of administering an effective amount of crystalline obeticholic acid according to any one of claims 1-9 or 87-98 or a pharmaceutical composition according to any one of claims 100-101.

104. The method according to any one of claims 102-103, wherein the disease or condition is selected from biliary atresia, cholestatic liver disease, chronic liver disease, nonalcoholic steatohepatitis (NASH), hepatitis C infection, alcoholic liver disease, primary biliary cirrhosis (PBC), liver damage due to progressive fibrosis, liver fibrosis, and cardiovascular diseases including atherosclerosis, arteriosclerosis, hypercholesteremia, and hyperlipidemia.

105. A method for lowering triglycerides in a subject comprise of administering an effective amount of obeticholic acid Form 1 according to any one of claims 60-86 or produced by a process according to any one of claims 10-50, or a pharmaceutical composition according to claim 99.

106. A method for lowering triglycerides in a subject comprise of administering an effective amount of crystalline obeticholic acid according to any one of claims 1-9 or 87-98 or a pharmaceutical composition according to any one of claims 100-101.

WE CLAIM:

1. A process of preparing obeticholic acid Form 1, comprising the step of converting crystalline obeticholic acid to obeticholic acid Form 1 and wherein obeticholic acid Form 1 is the non-crystalline form.

2. The process of claim 1, comprising the steps of

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and converting crystalline obeticholic acid to obeticholic acid Form 1.

3. The process of claim 2, comprising the steps of

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

4. The process of claim 3, comprising the steps of

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

5. The process of claim 4, comprising the steps of

reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

6. The process of claim 5, comprising the steps of:

reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester with $Li[N(CH(CH_3)_2)_2]$ and $Si(CH_3)_3Cl$ to form 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester,

reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

7. The process of claim 6, comprising the steps of:

reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid with CH_3OH and H_2SO_4 to form 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester,

reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester with $Li[N(CH(CH_3)_2)_2]$ and $Si(CH_3)_3Cl$ to form 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester,

reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid,

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid,

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid, and

converting crystalline obeticholic acid to obeticholic acid Form 1.

8. The process of claim 7, wherein converting crystalline obeticholic acid to obeticholic acid Form 1 comprises the step of dissolving crystalline obeticholic acid in aqueous NaOH solution and adding HCl.

9. The process of claim 7, wherein reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid is carried out at a temperature at about 85 °C to about 110 °C in a basic aqueous solution.

10. The process of claim 7, wherein reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid is carried out at a temperature at about 90 °C to about 110 °C.

11. The process of claim 7, wherein reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid is carried out at a temperature at about 20°C to about 60 °C.

12. The process of claim 7, wherein reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester is carried out in a polar aprotic solvent at a temperature at about -50 °C to about -70 °C in the presence of BF_3.

13. The process of claim 7, wherein reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester with $Li[N(CH(CH_3)_2)_2]$ and $Si(CH_3)_3Cl$ to form 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester is carried out in a polar aprotic solvent at a temperature at about -10 °C to about -30 °C.

14. The process of claim 7, wherein reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid with CH_3OH and H_2SO_4 to form 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester is heated for about 3 hours and the pH of the reaction mixture is adjusted with an aqueous basic solution.

15. A process of preparing crystalline obeticholic acid comprising precipitating said crystalline form from a solution comprising obeticholic acid.

16. The process of claim 15, wherein the solution comprises n-butyl acetate.

17. The process of claim 15, wherein the crystalline obeticholic acid is characterized by a differential scanning calorimetry thermogram having an endothermic peak at about 98 ± 2 °C.

18. The process of claim 15, wherein the crystalline obeticholic acid is characterized by a differential scanning calorimetry thermogram pattern substantially similar to figure 6.

19. The process of claim 15, wherein the crystalline obeticholic acid is characterized by a thermo-gravimetric analysis thermogram pattern substantially similar to figure 6.

20. A process of preparing obeticholic acid Form 1, comprising the steps of reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid with CH_3OH and H_2SO_4 to form 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester in which the reaction is heated for about 3 hours and the pH of the reaction mixture is adjusted with an aqueous basic solution;

reacting 3α-hydroxy-7-keto-5β-cholan-24-oic acid methyl ester with $Li[N(CH(CH_3)_2)_2]$ and $Si(CH_3)_3Cl$ to form 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester in which the carried out in a polar aprotic solvent at a temperature at about -10 °C to about -30 °C;

reacting 3α,7-ditrimethylsilyloxy-5β-chol-6-en-24-oic acid methyl ester with CH_3CHO to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester is which the carried out in a polar aprotic solvent at a temperature at about -50 °C to about -70 °C in the presence of BF_3;

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid methyl ester with NaOH to form E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid in which the reaction is carried out at a temperature at about 20°C to about 60 °C;

reacting E- or E/Z-3α-hydroxy-6-ethylidene-7-keto-5β-cholan-24-oic acid with Pd/C and hydrogen gas to form 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid is which the reaction is carried out at a temperature at about 90 °C to about 110 °C;

reacting 3α-hydroxy-6α-ethyl-7-keto-5β-cholan-24-oic acid with $NaBH_4$ to form crystalline obeticholic acid is carried out at a temperature at about 85 °C to about 110 °C in a basic aqueous solution; and

converting crystalline obeticholic acid to obeticholic acid Form 1 by dissolving crystalline obeticholic acid in aqueous NaOH solution and adding HCl.

and wherein obeticholic acid Form 1 is the non-crystalline form.