CLAIMS

WHAT IS CLAIMED IS:

1. A composition comprising:

an effective amount of niraparib to inhibit polyadenosine diphosphate ribose polymerase (PARP) when administered to a subject in need thereof;

wherein the composition is a pharmaceutical composition formulated as a tablet, and wherein the tablet is characterized by least one of the following:

(a) the tablet comprises less than about 0.2% by weight of any single niraparib degradation product;

(b) the tablet comprises less than about 0.2% by weight of any single niraparib degradation product after storage for about 1 month at about 40 °C and about 75% relative humidity (RH); and

(c) the tablet comprises less than about 0.2% by weight of any single niraparib degradation product after storage for about 2 months at about 40 °C and about 75% relative humidity (RH).

2. The composition of claim 1, wherein the tablet comprises less than about 0.2%, 0.1%, 0.09%, 0.08%, 0.07%, 0.06%, 0.05%, 0.04%, 0.03%, 0.02%, 0.01%, 0.005%, or 0.001% by weight of any single niraparib degradation product.

3. The composition of claim 1, wherein the tablet comprises less than about 0.2%, 0.1%, 0.09%, 0.08%, 0.07%, 0.06%, 0.05%, 0.04%, 0.03%, 0.02%, 0.01%, 0.005%, or 0.001% by weight of any single niraparib degradation product after storage for 1 month at 40 °C and 75% relative humidity (RH).

4. The composition of claim 1, wherein the tablet comprises less than about 0.2%, 0.1%, 0.09%, 0.08%, 0.07%, 0.06%, 0.05%, 0.04%, 0.03%, 0.02%, 0.01%, 0.005%, or 0.001% by weight of any single niraparib degradation product after storage for about 2 months at about 40 °C and about 75% relative humidity (RH).

5. A composition comprising:

an effective amount of niraparib to inhibit polyadenosine diphosphate ribose polymerase (PARP) when administered to a subject in need thereof;

wherein the composition is a pharmaceutical composition formulated as a tablet, and the tablet has at least one of the following:

(a) a weight of at least about 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1100, or 1200 mg;

(b) a thickness of at least about 4.0 mm; and

(c) a friability of less than about 2%;

wherein the effective amount of niraparib is from about 50 mg to about 350 mg based on the niraparib free base.

6. The composition of any one of claims 1-5, wherein the effective amount of niraparib is from about 75 mg to about 125 mg based on the niraparib free base.

7. The composition of any one of claims 1-5, wherein the effective amount of niraparib is about 50 mg, about 100 mg, or about 150 mg based on the niraparib free base.

8. The composition of claim 6 or 7, wherein the effective amount of niraparib is about 100 mg based on the niraparib free base.

9. The composition of any one of claims 5-8, wherein the tablet has a net weight of at least about 200 mg, at least about 210 mg, at least about 220 mg, at least about 230 mg, at least about 240 mg, at least about 250 mg, at least about 260 mg, at least about 270 mg, at least about 280 mg, at least about 290 mg, about 300 mg, at least about 310 mg, at least about 320 mg, at least about 330 mg, at least about 340 mg, at least about 350 mg, at least about 360 mg, at least about 370 mg, at least about 380 mg, at least about 390 mg, at least about 400 mg, at least about 410 mg, at least about 420 mg, at least about 430 mg, at least about 440 mg, at least about 450 mg, at least about 460 mg, at least about 470 mg, at least about 480 mg, at least about 490 mg, or at least about 500 mg.

10. The composition of any one of claims 5-9, wherein the tablet has a net weight of at least about 300 mg.

11. The composition of claim 10, wherein the tablet has a net weight of about 300 mg to about 450 mg.

12. The composition of claim 11, wherein the tablet has a net weight of about 300 mg to about 350 mg, about 350 mg to about 400 mg, or about 400 mg to about 450 mg.

13. The composition of any one of claims 1-5, wherein the effective amount of niraparib is from about 175 mg to about 225 mg based on the niraparib free base.

14. The composition of any one of claims 1-5, wherein the effective amount of niraparib is about 150 mg, 200 mg, or about 250 mg based on the niraparib free base.

15. The composition of any one of claims 1-5, wherein the effective amount of niraparib is about 200 mg based on the niraparib free base.

16. The composition of any one of claims 1-5 and 13-15, wherein the tablet has a net weight of at least about 500 mg, at least about 510 mg, at least about 520 mg, at least about 530 mg, at least about 540 mg, at least about 550 mg, at least about 560 mg, at least about 570 mg, at least about 580 mg, at least about 590 mg, at least about 600 mg, at least about 610 mg, at least about 620 mg, at least about 630 mg, at least about 640 mg, at least about 650 mg, at least about 660 mg, at least about 670 mg, at least about 680 mg, at least about 690 mg, at least about 700 mg, at least about 710 mg, at least about 720 mg, at least about 730 mg, at least about 740 mg, at least about 750 mg, at least about 760 mg, at least about 770 mg, at least about 780 mg, at least about 790 mg, or at least about 800 mg.

17. The composition of any one of claims 1-5 and 13-16, wherein the tablet has a net weight of at least 600 mg.

18. The composition of claim 17, wherein the tablet has a net weight of about 600 mg to about 750 mg.

19. The composition of claim 18, wherein the tablet has a net weight of about 600 mg to about 650 mg, about 650 mg to about 700 mg, or about 700 mg to about 750 mg.

20. The composition of any one of claims 1-5, wherein the effective amount of niraparib is from about 275 mg to about 325 mg based on the niraparib free base.

21. The composition of any one of claims 1-5, wherein the effective amount of niraparib is about 250 mg, about 300 mg, or about 350 mg based on the niraparib free base.

22. The composition of any one of claims 1-5, wherein the effective amount of niraparib is about 300 mg based on the niraparib free base.

23. The composition of any one of claims 1-5 and 20-22, wherein the tablet has a net weight of at least about 800 mg, at least about 810 mg, at least about 820 mg, at least about 830 mg, at least about 840 mg, at least about 850 mg, at least about 860 mg, at least about 870 mg, at

~~least about 880 mg, at least about 890 mg, at least about 900 mg, at least about 910 mg, at least about 920 mg, at least about 930 mg, at least about 940 mg, at least about 950 mg, at least about 960 mg, at least about 970 mg, at least about 980 mg, at least about 990 mg, at least about 1000 mg, at least about 1010 mg, at least about 1020 mg, at least about 1030 mg, at least about 1040 mg, at least about 1050 mg, at least about 1060 mg, at least about 1070 mg, at least about 1080 mg, at least about 1090 mg, at least about 1100 mg, at least about 1110 mg, at least about 1120 mg, at least about 1130 mg, at least about 1140 mg, at least about 1150 mg, at least about 1160 mg, at least about 1170 mg, at least about 1180 mg, at least about 1190 mg, or at least about 1200 mg.~~

~~24. The composition of any one of claims 1-5 and 20-23, wherein the tablet has a net weight of at least about 1000 mg.~~

~~25. The composition of claim 24, wherein the tablet has a net weight of about 1000 mg to about 1150 mg.~~

~~26. The composition of claim 25, wherein the tablet has a net weight of about 1000 mg to about 1050 mg, of about 1050 mg to about 1100 mg, or about 1100 mg to about 1150 mg.~~

~~27. The composition of any one of claims 1-26, wherein the tablet has a thickness of at least 4.0 mm, at least 4.1 mm, at least 4.2 mm, at least 4.3 mm, at least 4.4, at least 4.5 mm, at least 4.6 mm, at least 4.7 mm, at least 4.8 mm, at least 4.9 mm, at least 5.0 mm, at least 5.1 mm, at least 5.2 mm, at least 5.3 mm, at least 5.4 mm, at least 5.5 mm, at least 5.6 mm, at least 5.7 mm, at least 5.8 mm, at least 5.9 mm, at least 6.0 mm, at least 6.1 mm, at least 6.2 mm, at least 6.3 mm, at least 6.4 mm, at least 6.5 mm, at least 6.6 mm, at least 6.7 mm, at least 6.8, at least 6.9 mm, at least 7.0 mm, at least 7.1 mm, at least 7.2 mm, at least 7.3 mm, at least 7.4 mm, at least 7.5 mm, at least 7.6 mm, at least 7.7 mm, at least 7.8 mm, at least 7.9 mm, at least 8.0 mm, at least 8.5 mm, at least 9.0 mm, at least 9.5 mm, or at least 10 mm.~~

~~28. The composition of any one of claims 1-27, wherein the tablet has a friability of less than 2%, less than 1.9%, less than 1.8%, less than 1.7%, less than 1.6%, less than 1.5%, less than 1.4%, less than 1.3%, less than 1.2%, less than 1.1%, less than 1.0%, less than 0.9%, less than 0.8%, less than 0.7%, less than 0.6%, less than 0.5%, less than 0.4%, less than 0.3%, less than 0.2%, or less than 0.1%.~~

29. The composition of any one of claims 1-28, wherein the niraparib comprises niraparib free base or a pharmaceutically acceptable salt thereof.

30. The composition of claim 29, wherein the pharmaceutically acceptable salt of niraparib is niraparib tosylate.

31. A composition comprising a tablet comprising

(a) an effective amount of niraparib to inhibit polyadenosine diphosphate ribose polymerase (PARP) when administered to a subject in need thereof; and

(b) silicon dioxide;

wherein the effective amount of niraparib is from about 50 mg to about 350 mg based on the niraparib free base.

32. The composition of claim 31, wherein the effective amount of niraparib is from about 75 mg to about 125 mg based on the niraparib free base.

33. The composition of claim 31, wherein the effective amount of niraparib is about 50 mg, about 100 mg, or about 150 mg based on the niraparib free base.

34. The composition of claim 31, wherein the effective amount of niraparib is about 100 mg based on the niraparib free base.

35. The composition of claim 31, wherein the effective amount of niraparib is from about 175 mg to about 225 mg based on the niraparib free base.

36. The composition of claim 31, wherein the effective amount of niraparib is about 150 mg, 200 mg, or about 250 mg based on the niraparib free base.

37. The composition of claim 31, wherein the effective amount of niraparib is about 200 mg based on the niraparib free base.

38. The composition of claim 31, wherein the effective amount of niraparib is from about 275 mg to about 325 mg based on the niraparib free base.

39. The composition of claim 31, wherein the effective amount of niraparib is about 250 mg, about 300 mg, or about 350 mg based on the niraparib free base.

~~40. The composition of claim 31, wherein the effective amount of niraparib is about 300 mg based on the niraparib free base.~~

~~41. The composition of any one of claims 31-40, wherein the niraparib comprises niraparib free base or a pharmaceutically acceptable salt thereof.~~

~~42. The composition of claim 41, wherein the pharmaceutically acceptable salt of niraparib is niraparib tosylate.~~

~~43. A composition comprising niraparib in an amount of about 50 mg to about 350 mg based on the niraparib free base,~~

~~wherein the composition is a pharmaceutical composition formulated as a tablet comprising an intragranular phase and an extragranular phase, and wherein:~~

~~(a) at least one component of the intragranular phase is a diluent, a binder, a disintegrant, a glidant, or a lubricant; and/or~~

~~(b) at least one component of the extragranular phase is a disintegrant, a glidant, or a lubricant.~~

~~44. A composition comprising:~~

~~an effective amount of niraparib to inhibit polyadenosine diphosphate ribose polymerase (PARP) when administered to a subject in need thereof;~~

~~wherein the composition is a pharmaceutical composition formulated as a tablet;~~

~~wherein the tablet further comprises an intragranular phase and an extragranular phase; and the tablet has at least one of the following:~~

~~(a) the amount of components used to form the intragranular phase is about 50% to about 98% by weight of the tablet composition; and~~

~~(b) the amount of components used to form the extragranular phase is about 2% to about 50% by weight of the tablet composition.~~

~~45. The composition of claim 43 or 44, wherein the amount of components used to form the intragranular phase is about 50% to about 98% by weight of the tablet composition.~~

~~46. The composition of claim 43 or 44, wherein the amount of components used to form the intragranular phase is about 85% to about 98% by weight of the tablet composition.~~

~~47. The composition of claim 43 or 44, wherein the amount of components used to form the intragranular phase is about 90% to about 98% by weight of the tablet composition.~~

~~48. The composition of claim 47, wherein the amount of components used to form the intragranular phase is at least about 90%, about 91%, about 92%, about 93%, about 94%, about 95%, about 96%, or about 97%.~~

~~49. The composition of claim 47 or 48, wherein the amount of components used to form the intragranular phase is about 90%, about 91%, about 92%, about 93%, about 94%, about 95%, about 96%, or about 97%.~~

~~50. The composition of claim 43 or 44, wherein the amount of components used to form the intragranular phase is about 92.5% to about 97.5% by weight of the tablet composition.~~

~~51. The composition of claim 43 or 44, wherein the amount of components used to form the intragranular phase is about 95% by weight of the tablet composition.~~

~~52. The composition of any one of claims 43-51, wherein the amount of components used to form the extragranular phase is about 2% to about 50% by weight of the tablet composition.~~

~~53. The composition of any one of claims 43-51, wherein the amount of components used to form the extragranular phase is about 2% to about 15% by weight of the tablet composition.~~

~~54. The composition of any one of claims 43-51, wherein the amount of components used to form the extragranular phase is about 2% to about 10% by weight of the tablet composition.~~

~~55. The composition of claim 54, wherein the amount of components used to form the extragranular phase is no more than about 9%, about 8%, about 7%, about 6%, about 5%, about 4%, or about 3%.~~

~~56. The composition of claim 54 or 55, wherein the amount of components used to form the extragranular phase is about 2%, about 3%, about 4%, or about 5%.~~

~~57. The composition of any one of claims 43-51, wherein the amount of components used to form the extragranular phase is about 2.5% to about 7.5% by weight of the tablet composition.~~

58. The composition of any one of claims 43-51, wherein the amount of components used to form the extragranular phase is about 5% by weight of the tablet composition.

59. The composition of any one of claims 1-58, comprising a first diluent.

60. The composition of any one of claims 1-59, comprising a second diluent.

61. The composition of any one of claims 1-60, comprising a lubricant.

62. The composition of any one of claims 1-61, comprising a binder.

63. A composition comprising niraparib tosylate monohydrate in an amount of about 100 mg to about 550 mg,

wherein the composition is a pharmaceutical composition formulated as a tablet comprising an intragranular phase and an extragranular phase, and wherein

the composition comprises niraparib tosylate monohydrate in an amount that is about 40-50% by weight of the tablet composition.

64. The composition of claim 63, wherein the intragranular phase comprises a diluent in an amount that is about 7.5-15%, about 8-14%, or about 9-11% by weight of the tablet composition.

65. The composition of claim 64, wherein the intragranular phase comprises a second diluent in an amount that is about 25-40%, about 30-40%, or about 30-35% by weight of the tablet composition.

66. The composition of any one of claims 63-65, wherein the intragranular phase comprises a binder in an amount that is about 1-3% by weight of the tablet composition.

67. The composition of any one of claims 63-66, wherein the intragranular phase comprises a disintegrant in an amount that is about 0.1-2% or about 0.5%-1.5% by weight of the tablet composition.

68. The composition of any one of claims 63-67, wherein the intragranular phase comprises a glidant, adsorbant, or absorbant in an amount that is about 1-5% or about 2-4% by weight of the tablet composition.

69. The composition of any one of claims 63-68, wherein the intragranular phase comprises a lubricant in an amount that is about 0.1-2% by weight of the tablet composition.

70. The composition of any one of claims 63-69, wherein the extragranular phase comprises a distintegrant in an amount that is about 0.1-2% by weight of the tablet composition.

71. The composition of any one of claims 63-70, wherein the extragranular phase comprises a glidant or adsorbant or absorbant in an amount that is about 0.1-2% by weight of the tablet composition.

72. The composition of any one of claims 63-71, wherein the extragranular phase comprises a lubricant in an amount that is about 0.1-2% by weight of the tablet composition.

73. A composition that is a pharmaceutical composition formulated as a tablet comprising the following components on a weight percentage basis:

(a) in an intragranular portion:

(i) about 40-50% niraparib tosylate monohydrate;

(ii) about 8-14% of a first diluent;

(iii) about 30-40% of a second diluent;

(iv) about 1-3% of a binder;

(v) about 0.1-2% of a disintegrant;

(vi) about 2-4% of a glidant or adsorbant or absorbant; and

(vii) about 0.1-2% of a lubricant;

(b) in an extragranular portion:

(i) about 0.1-2% of a disintegrant;

(ii) about 0.1-2% of a glidant or adsorbant or absorbant; and

(iii) about 0.1-2% of a lubricant.

74. A composition comprising a tablet comprising the following components on a weight percentage basis:

(a) in an intragranular portion:

(i) 40-50% niraparib tosylate monohydrate;

(ii) 9-11% of a first diluent;

(iii) 30-40% of a second diluent;

(iv) 1-3% of a binder;

(v) 0.1-2% of a disintegrant;

(vi) 2-4% of a glidant or adsorbant or absorbant; and

(vii) 0.1-2% of a lubricant;

(b) in an extragranular portion:

(i) 0.1-2% of a disintegrant;

(ii) 0.1-2% of a glidant or adsorbant or absorbant; and

(iii) 0.1-2% of a lubricant.

75. The composition of claim 74, wherein the lubricant is magnesium stearate.

76. The composition of claim 74 or claim 75, wherein the disintegrant is crospovidone.

77. The composition of any one of claims 74-76, wherein the glidant is silicon dioxide, optionally wherein the glidant is intermediate meso-porous silica, further optionally wherein the intermediate meso-porous silica comprises syloid FP-244.

78. A composition comprising a tablet comprising

(a) an effective amount of niraparib to inhibit polyadenosine diphosphate ribose polymerase (PARP) when administered to a subject in need thereof;

(b) a first diluent selected from lactose monohydrate, lactose anhydrous, mannitol, and calcium phosphate dibasic;

(c) magnesium stearate;

(d) a second diluent selected from microcrystalline cellulose, starch, polyethylene oxide, and hydroxypropyl methylcellulose (HPMC); and

(e) a binder selected from povidone (PVP), hydroxypropyl cellulose (HPC), and hydroxypropyl methylcellulose (HPMC).

79. The composition of any one of claims 59-78, wherein the first diluent is lactose monohydrate.

80. The composition of claim 79, wherein the lactose monohydrate is spray dried or crystalline.

81. The composition of claim 79, wherein the lactose monohydrate is engineered or non-enginered.

82. The composition of claim 81, wherein engineered lactose monohydrate is spray dried lactose monohydrate or non-engineered lactose monohydrate is powder lactose monohydrate.

83. The composition of any one of claims 59-78, wherein the first diluent is mannitol.

84. The composition of claim 83, wherein the mannitol is spray-dried or crystalline.

85. The composition of any one of claims 59-78, wherein the first diluent is calcium phosphate dibasic.

86. The composition of any one of claims 60-85, wherein the second diluent is microcrystalline cellulose.

87. The composition of any one of claims 60-85, wherein the second diluent is starch, polyethylene oxide, or hydroxypropyl methylcellulose (HPMC).

88. The composition of any one of claims 62-87, wherein the binder is povidone (PVP).

89. The composition of any one of claims 62-87, wherein the binder is hydroxypropyl cellulose (HPC).

90. The composition of any one of claims 62-87, wherein the binder is hydroxypropyl methylcellulose (HPMC).

91. The composition of any one of claims 1-90, wherein the composition comprises a disintegrant.

92. The composition of claim 91, wherein the disintegrant is crospovidone or croscarmellose.

93. The composition of claim 92, wherein the croscarmellose is croscarmellose sodium.

94. The composition of claim 92, wherein the disintegrant is crospovidone.

95. The composition of any one of claims 1-94, wherein the composition comprises a large meso-porous silica excipient as an adsorbant or absorbant.

96. The composition of claim 95, wherein the large meso-porous silica excipient absorbs water.

97. The composition of any one of claims 1-94, wherein the composition further comprises an intermediate meso-porous silica excipient as a glidant.

98. The composition of any one of claim 97, wherein the intermediate meso-porous silica comprises syloid FP-244.

~~99. The composition of any one of claims 1-98, wherein the composition comprises silicon dioxide.~~

~~100. The composition of claim 99, wherein the silicon dioxide is present in an amount of about 0.1% to about 10% by weight.~~

~~101. The composition of claim 99, wherein the silicon dioxide is present in an amount of about 0.1% to about 5% by weight.~~

~~102. The composition of claim 99, wherein the silicon dioxide is present in an amount of about 0.1%, about 0.2%, about 0.3%, about 0.4%, about 0.5%, about 0.6, about 0.7%, about 0.8%, about 0.9%, about 1%, about 1.5%, about 2%, about 2.5%, about 3%, about 3.5%, about 4%, about 4.5%, or about 5% by weight.~~

~~103. The composition of any one of claims 1-102, wherein the composition comprises an intragranular phase.~~

~~104. The composition of claim 103, wherein the intragranular phase comprises silicon dioxide.~~

~~105. The composition of claim 104, wherein the silicon dioxide in the intragranular phase is present in an amount of about 0.1% to about 10% by weight.~~

~~106. The composition of claim 104, wherein the silicon dioxide in the intragranular phase is present in an amount of about 0.1% to about 5% by weight.~~

~~107. The composition of claim 104, wherein the silicon dioxide in the intragranular phase is present in an amount of about 0.1%, about 0.2%, about 0.3%, about 0.4%, about 0.5%, about 0.6, about 0.7%, about 0.8%, about 0.9%, about 1%, about 1.5%, about 2%, about 2.5%, about 3%, about 3.5%, about 4%, about 4.5%, or about 5% by weight.~~

~~108. The composition of any one of claims 103-107, wherein the intragranular phase does not comprise magnesium stearate.~~

~~109. The composition of claim 108, wherein the intragranular phase comprises niraparib, lactose monohydrate, microcrystalline cellulose, crospovidone, and povidone.~~

~~110. The composition of claim 108, wherein the intragranular phase comprises niraparib, lactose monohydrate, microcrystalline cellulose, croscarmellose, and hydroxypropyl cellulose (HPC).~~

~~111. The composition of claim 108, wherein the intragranular phase comprises niraparib, lactose monohydrate, microcrystalline cellulose, croscarmellose, and hydroxypropyl methylcellulose (HMPC).~~

~~112. The composition of claim 108, wherein the intragranular phase comprises niraparib, lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, and a large meso-porous silica excipient as an adsorbant or absorbant or an intermediate meso-porous silica excipient as a glidant.~~

~~113. The composition of claim 108, wherein the intragranular phase comprises niraparib, lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, and a large meso-porous silica excipient as an adsorbant or absorbant.~~

~~114. The composition of claim 108, wherein the intragranular phase comprises niraparib, lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, and an intermediate meso-porous silica excipient as a glidant.~~

~~115. The composition of any one of claims 103-107, wherein the intragranular phase comprises magnesium stearate.~~

~~116. The composition of claim 115, wherein the intragranular phase comprises niraparib, microcrystalline cellulose, calcium phosphate dibasic, crospovidone, povidone, and magnesium stearate.~~

~~117. The composition of claim 115, wherein the intragranular phase comprises niraparib, microcrystalline cellulose, mannitol, croscarmellose, hydroxypropyl cellulose (HPC), and magnesium stearate.~~

~~118. The composition of claim 115, wherein the intragranular phase comprises niraparib, microcrystalline cellulose, mannitol, croscarmellose, hydroxypropyl methylcellulose (HPMC), and magnesium stearate.~~

~~119. The composition of claim 115, wherein the intragranular phase comprises niraparib, microcrystalline cellulose, mannitol, crospovidone, povidone, and magnesium stearate.~~

~~120. The composition of claim 115, wherein the intragranular phase comprises niraparib, lactose monohydrate, microcrystalline cellulose, crospovidone, and povidone.~~

~~121. The composition of claim 115, wherein the intragranular phase comprises niraparib, lactose monohydrate, microcrystalline cellulose, croscarmellose, and hydroxypropyl cellulose (HPC).~~

~~122. The composition of any one of claims 1-121, wherein the composition further comprises an extragranular phase.~~

~~123. The composition of claim 122, wherein the extragranular phase comprises magnesium stearate.~~

~~124. The composition of claim 122 or 123, wherein the extragranular phase comprises crospovidone.~~

~~125. The composition of claim 122 or 123, wherein the extragranular phase comprises croscarmellose.~~

~~126. The composition of any one of claims 122-125, wherein the extragranular phase comprises silicon dioxide.~~

~~127. The composition of claim 126, wherein the silicon dioxide in the extragranular phase is present in an amount of about 0.1% to about 10% by weight.~~

~~128. The composition of claim 126, wherein the silicon dioxide in the extragranular phase is present in an amount of about 0.1% to about 5% by weight.~~

~~129. The composition of claim 126, wherein the silicon dioxide in the extragranular phase is present in an amount of about 0.1% to about 2.5% by weight.~~

~~130. The composition of claim 126, wherein the silicon dioxide in the extragranular phase is present in an amount of about 0.1%, about 0.2%, about 0.3%, about 0.4%, about 0.5%, about 0.6, about 0.7%, about 0.8%, about 0.9%, about 1%, about 1.5%, about 2%, about 2.5%, about 3%, about 3.5%, about 4%, about 4.5%, or about 5% by weight.~~

~~131. A composition that is a tablet comprising any one of Formulations 1-42.~~

~~132. The composition of claim 131, wherein the tablet comprises any one of Formulations 1-6.~~

~~133. The composition of claim 131, wherein the tablet comprises any one of Formulations 7-18.~~

~~134. The composition of claim 131, wherein the tablet comprises any one of Formulations 19-30.~~

~~135. The composition of claim 131, wherein the tablet comprises any one of Formulations 31-42.~~

~~136. The composition of any one of claims 1-135, wherein the tablet has a disintegration time of about 30 seconds to about 300 seconds.~~

~~137. The composition of any one of claims 1-135, wherein the tablet has a disintegration time of about 30 seconds to about 200 seconds.~~

~~138. The composition of any one of claims 1-135, wherein the tablet has a disintegration time of about 30 seconds to about 150 seconds.~~

~~139. The composition of any one of claims 1-135, wherein the tablet has a disintegration time of about 30 seconds, about 40 seconds, about 50 seconds, about 60 seconds, about 70 seconds, about 80 seconds, about 90 seconds, about 100 seconds, about 110 seconds, about 120 seconds, about 130 seconds, about 140 seconds, about 150 seconds, about 160 seconds, about 170 seconds, about 180 seconds, about 190 seconds, about 200 seconds, about 210 seconds, about 220 seconds, about 230 seconds, about 240 seconds, about 250 seconds, about 260 seconds, about 270 seconds, about 280 seconds, about 290 seconds, or about 300 seconds.~~

~~140. The composition of any one of claims 1-139, wherein the composition comprises less than 10% by weight of water.~~

~~141. The composition of any one of claims 1-140, wherein the composition comprises less than 10% by weight of water after storage for 1 month at 40 °C and 75% relative humidity (RH).~~

~~142. The composition of any one of claims 1-141, wherein the composition comprises less than 10% by weight of water after storage for 2 months at 40 °C and 75% relative humidity (RH).~~

~~143. The composition of any one of claims 1-142, further comprising a coating layer.~~

144. The composition of claim 143, wherein the coating layer comprises polyvinyl alcohol, titanium dioxide, polyethylene glycol, and/or talc.

145. The composition of claim 143 or 144, wherein the coating layer is present in an amount of about 0.1% to about 5% by weight of the composition.

146. A method of making a tablet from wet granulation comprising niraparib comprising:

(a) forming an intragranular phase comprising

i) combining niraparib, lactose monohydrate, and microcrystalline cellulose to form a composition comprising niraparib, lactose monohydrate, and microcrystalline cellulose; and

ii) wet granulating the composition comprising niraparib, lactose monohydrate, and microcrystalline cellulose to form granules;

(b) forming an extragranular phase comprising

iii) combining the granules with at least one pharmaceutically acceptable excipient to form a mixture; and

(c) forming a tablet by compressing the mixture obtained from step iii).

147. The method of claim 146, wherein the wet granulating from step ii) further comprises adding a binder.

148. The method of claim 147, wherein the binder is a liquid binder.

149. The method of claim 148, wherein the liquid binder is dissolved povidone.

150. The method of claim 148, wherein the liquid binder is dissolved starch, dissolved hydroxypropyl cellulose (HPC), dissolved hydroxypropyl methylcellulose (HPMC), or liquid polyethylene glycol (PEG).

151. The method of claim 148, wherein the liquid binder is a melted binder.

152. The method of claim 151, wherein the melted binder is a hydrophilic polyethylene glycol (PEG), poloxamer, hydrophobic fatty acid, fatty alcohol, wax, hydrogenated vegetable oil, or glyceride.

153. The method of claim 147, wherein the binder is a dry binder.

154. The method of claim 153, wherein the dry binder is hydroxypropyl cellulose (HPC).

155. The method of claim 153, wherein the dry binder is hydroxypropyl methylcellulose (HPMC).

156. The method of claim 153, wherein the dry binder is povidone (PVP) or starch.

157. The method of any one of claims 146-156, wherein the wet granulating from step ii) further comprises wet-sieving.

158. The method of any one of claims 146-157, wherein the wet granulating from step ii) further comprises drying and dry-sieving.

159. A method of making a tablet from moisture-activated dry granulation comprising niraparib comprising:

(a) forming an intragranular phase comprising

i) combining niraparib, lactose monohydrate, and microcrystalline cellulose to form a composition comprising niraparib, lactose monohydrate, and microcrystalline cellulose; and

ii) granulating the composition comprising niraparib, lactose monohydrate, and microcrystalline cellulose to form granules;

(b) forming an extragranular phase comprising

iii) combining the granules with at least one pharmaceutically acceptable excipient to form a mixture; and

(c) forming a tablet by compressing the mixture obtained from step iii).

160. The method of claim 159, wherein the granulating from step ii) further comprises adding a binder.

161. The method of claim 160, wherein the binder is a liquid binder.

162. The method of claim 161, wherein the liquid binder is dissolved povidone.

163. The method of claim 161, wherein the liquid binder is water, dissolved starch, dissolved hydroxypropyl cellulose (HPC), dissolved hydroxypropyl methylcellulose (HPMC), or liquid polyethylene glycol (PEG).

164. The method of claim 159, wherein the composition further comprises a dry binder.

165. The method of claim 164, wherein water is added to the composition comprising the dry binder.

166. The method of any one of claims 159-165, wherein the granulating from step ii) further comprises drying and dry sieving.

167. The method of claim 166, wherein drying comprises the addition of a glidant.

168. The method of claim 167, wherein the glidant is silicon dioxide.

169. The method of claim 167, wherein the glidant is silicon dioxide, tribasic calcium phosphate, calcium silicate, cellulose, magnesium silicate, magnesium trisilicate, starch, talc, or mixtures thereof.

170. A method of making a tablet from dry granulation comprising niraparib comprising:

(a) forming an intragranular phase comprising

i) combining niraparib, a diluent selected from mannitol and calcium phosphate dibasic, microcrystalline cellulose, and magnesium stearate to form a composition comprising niraparib, the diluent selected from mannitol and calcium phosphate dibasic, microcrystalline cellulose, and magnesium stearate; and

ii) dry granulating the composition comprising niraparib, the diluent selected from mannitol and calcium phosphate dibasic, microcrystalline cellulose, and magnesium stearate to form granules;

(b) forming an extragranular phase comprising

iii) combining the granules with at least one pharmaceutically acceptable excipient to form a mixture; and

(c) forming a tablet by compressing the mixture obtained from step iii).

171. The method of claim 170, wherein the composition further comprises a dry binder.

172. The method of claim 171, wherein water is added to the composition comprising the dry binder.

173. The method of any one of claims 170-172, wherein combining niraparib, a diluent selected from mannitol and calcium phosphate dibasic, microcrystalline cellulose, and magnesium stearate to form a composition comprising niraparib, the diluent selected from mannitol and calcium phosphate dibasic, microcrystalline cellulose, and magnesium stearate from step i) further comprises blending the niraparib, a diluent selected from mannitol and calcium phosphate dibasic, microcrystalline cellulose, and magnesium stearate.

~~174. The method of any one of claims 170-173, wherein dry granulating from step ii) comprises slugging and milling.~~

~~175. The method of any one of claims 170-174, wherein the ribbon thickness is from about 0.1 mm to about 2 mm.~~

~~176. The method of any one of claims 146-175, wherein the composition from step i) further comprises silicon dioxide.~~

~~177. The method of any one of claims 146-176, wherein the at least one pharmaceutically acceptable excipient for combining the granules with at least one pharmaceutically acceptable excipient to form a mixture from step iii) is silicon dioxide.~~

~~178. The method of any one of claims 146-177, wherein the at least one pharmaceutically acceptable excipient for combining the granules with at least one pharmaceutically acceptable excipient to form a mixture from step iii) is magnesium stearate.~~

~~179. The method of any one of claims 146-178, wherein combining the granules with at least one pharmaceutically acceptable excipient to form a mixture from step iii) comprises blending the granules with at least one pharmaceutically acceptable excipient.~~

~~180. The method of any one of claims 146-179, wherein the composition from step i) is a blend composition.~~

~~181. The method of any one of claims 146-180, wherein the amount of components used to form the intragranular phase is about 50% to about 98% by weight of the tablet composition.~~

~~182. The method of any one of claims 146-180, wherein the amount of components used to form the intragranular phase is about 85% to about 98% by weight of the tablet composition.~~

~~183. The method of any one of claims 146-180, wherein the amount of components used to form the intragranular phase is about 90% to about 98% by weight of the tablet composition.~~

~~184. The method of any one of claims 146-180, wherein the amount of components used to form the intragranular phase is about 92.5% to about 97.5% by weight of the tablet composition.~~

~~185. The method of any one of claims 146-180, wherein the amount of components used to form the intragranular phase is about 95% by weight of the tablet composition.~~

186. The method of any one of claims 146-185, wherein the amount of components used to form the extragranular phase is about 2% to about 50% by weight of the tablet composition.

187. The method of any one of claims 146-185, wherein the amount of components used to form the extragranular phase is about 2% to about 15% by weight of the tablet composition.

188. The method of any one of claims 146-185, wherein the amount of components used to form the extragranular phase is about 2% to about 10% by weight of the tablet composition.

189. The method of any one of claims 146-185, wherein the amount of components used to form the extragranular phase is about 2.5% to about 7.5% by weight of the tablet composition.

190. The method of any one of claims 146-185, wherein the amount of components used to form the extragranular phase is about 5% by weight of the tablet composition.

191. The method of any one of claims 146-190, wherein the granules have a bulk density of about 0.2 to about 0.7 g/cm^3.

192. The method of any one of claims 146-191, wherein the granules have a tapped density of about 0.3 to about 0.9 g/cm^3.

193. A method of making a composition comprising niraparib comprising:

(a) forming an intragranular phase comprising

i) combining niraparib and at least one pharmaceutically acceptable excipient to form a composition comprising niraparib and at least one pharmaceutically acceptable excipient; and

ii) granulating the composition comprising niraparib and at least one pharmaceutically acceptable excipient to form granules;

(b) forming an extragranular phase comprising

iii) combining the granules with at least one pharmaceutically acceptable excipient to form a mixture; and

(c) forming a tablet by compressing the mixture obtained from step iii);

wherein the tablet has at least one of the following:

(1) the amount of components used to form the intragranular phase is about 50% to about 98% by weight of the tablet composition; and

(2) the amount of components used to form the extragranular phase is about 2% to about 50% by weight of the tablet composition; and

wherein the composition is a pharmaceutical composition formulated as a tablet.

194. The method of claim 193, wherein the amount of components used to form the intragranular phase is about 50% to about 98% by weight of the tablet composition.

195. The method of claim 193, wherein the amount of components used to form the intragranular phase is about 85% to about 98% by weight of the tablet composition.

196. The method of claim 193, wherein the amount of components used to form the intragranular phase is about 90% to about 98% by weight of the tablet composition.

197. The method of claim 193, wherein the amount of components used to form the intragranular phase is about 92.5% to about 97.5% by weight of the tablet composition.

198. The method of claim 193, wherein the amount of components used to form the intragranular phase is about 95% by weight of the tablet composition.

199. The method of any one of claims 193-198, wherein the amount of components used to form the extragranular phase is about 2% to about 50% by weight of the tablet composition.

200. The method of any one of claims 193-198, wherein the amount of components used to form the extragranular phase is about 2% to about 15% by weight of the tablet composition.

201. The method of any one of claims 193-198, wherein the amount of components used to form the extragranular phase is about 2% to about 10% by weight of the tablet composition.

202. The method of any one of claims 193-198, wherein the amount of components used to form the extragranular phase is about 2.5% to about 7.5% by weight of the tablet composition.

203. The method of any one of claims 193-198, wherein the amount of components used to form the extragranular phase is about 5% by weight of the tablet composition.

204. The method of any one of claims 193-203, wherein the at least one pharmaceutically acceptable excipient from step i) is microcrystalline cellulose.

205. The method of any one of claims 193-204, wherein the at least one pharmaceutically acceptable excipient from step i) is lactose monohydrate, lactose anhydrous, mannitol, or calcium phosphate dibasic.

206. The method of any one of claims 193-205, wherein the at least one pharmaceutically acceptable excipient from step i) is magnesium stearate.

207. The method of any one of claims 193-206, wherein the at least one pharmaceutically acceptable excipient from step i) is silicon dioxide

208. The method of any one of claims 193-207, wherein the granulating from step ii) is wet granulating.

209. The method of claim 208, wherein the wet granulating further comprises adding a binder.

210. The method of claim 209, wherein the binder is a liquid binder.

211. The method of claim 210, wherein the liquid binder is dissolved povidone.

212. The method of claim 210, wherein the liquid binder is dissolved starch, dissolved hydroxypropyl cellulose (HPC), dissolved hydroxypropyl methylcellulose (HPMC), or liquid polyethylene glycol (PEG).

213. The method of claim 210, wherein the liquid binder is a melted binder.

214. The method of claim 213, wherein the melted binder is a hydrophilic polyethylene glycol (PEG), poloxamer, hydrophobic fatty acid, fatty alcohol, wax, hydrogenated vegetable oil, or glyceride.

215. The method of claim 214, wherein the binder is a dry binder.

216. The method of claim 215, wherein the dry binder is hydroxypropyl cellulose (HPC).

217. The method of claim 215, wherein the dry binder is hydroxypropyl methylcellulose (HPMC).

218. The method of claim 215, wherein the dry binder is povidone (PVP) or starch.

219. The method of any one of claims 208-218, wherein the wet-granulating from step ii) further comprises wet-sieving.

~~220. The method of any one of claims 208-219, wherein the wet granulating from step ii) further comprises drying and dry sieving.~~

~~221. The method of claim 220, wherein drying comprises the addition of a glidant.~~

~~222. The method of any one of claims 193-207, wherein the granulating from step ii) is dry granulating.~~

~~223. The method of claim 222, wherein the dry granulating comprises slugging and milling.~~

~~224. The method of any one of claims 193-223, wherein the at least one pharmaceutically acceptable excipient for combining the granules with at least one pharmaceutically acceptable excipient to form a mixture from step iii) is silicon dioxide.~~

~~225. The method of any one of claims 193-224, wherein the at least one pharmaceutically acceptable excipient for combining the granules with at least one pharmaceutically acceptable excipient to form a mixture from step iii) is magnesium stearate.~~

~~226. The method of any one of claims 146-225 used to prepare a composition of any one of claims 1-145.~~

~~227. A method of treating cancer, comprising administering to a subject in need thereof an effective amount of a composition according to any one of claims 1-145.~~

~~228. The method of claim 227, wherein the cancer is selected from the group consisting of ovarian cancer, breast cancer, cervical cancer, endometrial cancer, prostate cancer, testicular cancer, pancreatic cancer, esophageal cancer, head and neck cancer, gastric cancer, bladder cancer, lung cancer, bone cancer, colon cancer, rectal cancer, thyroid cancer, brain and central nervous system cancers, glioblastoma, neuroblastoma, neuroendocrine cancer, rhabdoid cancer, keratoacanthoma, epidermoid carcinoma, seminoma, melanoma, sarcoma, bladder cancer, liver cancer, kidney cancer, myeloma, lymphoma, and combinations thereof.~~

~~229. The method of claims 227 or 228, wherein the cancer is selected from the group consisting of ovarian cancer, fallopian tube cancer, primary peritoneal cancer, and combinations thereof.~~

1. A composition comprising niraparib in an amount of about 50 mg to about 350 mg based on the niraparib free base,

wherein the composition is a pharmaceutical composition formulated as a tablet comprising an intragranular phase and an extragranular phase, and wherein:

(a) at least one component of the intragranular phase is a diluent, a binder, a disintegrant, a glidant, or a lubricant; and/or

(b) at least one component of the extragranular phase is a disintegrant, a glidant, or a lubricant; and

wherein the composition comprises a binder.

2. A composition comprising niraparib tosylate monohydrate in an amount of about 100 mg to about 550 mg,

wherein the composition is a pharmaceutical composition formulated as a tablet comprising an intragranular phase and an extragranular phase, and wherein

the composition comprises niraparib tosylate monohydrate in an amount that is about 40-50% by weight of the tablet composition; and

wherein the composition comprises a binder.

3. The composition of claim 2, wherein the intragranular phase comprises a diluent in an amount that is about 7.5-15%, about 8-14%, or about 9-11% by weight of the tablet composition.

4. The composition of claim 3, wherein the intragranular phase comprises a second diluent in an amount that is about 25-40%, about 30-40%, or about 30-35% by weight of the tablet composition.

5. The composition of any one of claims 2-4, wherein the intragranular phase comprises a binder in an amount that is about 1-3% by weight of the tablet composition.

6. The composition of any one of claims 2-5, wherein the intragranular phase comprises a disintegrant in an amount that is about 0.1-2% or about 0.5%-1.5% by weight of the tablet composition.

7. The composition of any one of claims 2-6, wherein the intragranular phase comprises a glidant, adsorbant, or absorbant in an amount that is about 1-5% or about 2-4% by weight of the tablet composition.

8. The composition of any one of claims 2-7, wherein the intragranular phase comprises a lubricant in an amount that is about 0.1-2% by weight of the tablet composition.

9. The composition of any one of claims 2-8, wherein the extragranular phase comprises a distintegrant in an amount that is about 0.1-2% by weight of the tablet composition.

10. The composition of any one of claims 2-9, wherein the extragranular phase comprises a glidant or adsorbant or absorbant in an amount that is about 0.1-2% by weight of the tablet composition.

11. The composition of any one of claims 2-10, wherein the extragranular phase comprises a lubricant in an amount that is about 0.1-2% by weight of the tablet composition.

12. A composition in the form of a tablet comprising the following components on a weight percentage basis:

(a) in an intragranular portion:

(i) 40-50% niraparib tosylate monohydrate;

(ii) 9-11% of a first diluent;

(iii) 30-40% of a second diluent;

(iv) 1-3% of a binder;

(v) 0.1-2% of a disintegrant;

(vi) 2-4% of a glidant or adsorbant or absorbant; and

(vii) 0.1-2% of a lubricant;

(b) in an extragranular portion:

(i) 0.1-2% of a disintegrant;

(ii) 0.1-2% of a glidant or adsorbant or absorbant; and

(iii) 0.1-2% of a lubricant.

13. The composition of claim 12, wherein the lubricant is magnesium stearate.

14. The composition of claim 12 or claim 13, wherein the disintegrant is crospovidone.

15. The composition of any one of claims 13-14, wherein the glidant is silicon dioxide, optionally wherein the glidant is intermediate meso-porous silica, further optionally wherein the intermediate meso-porous silica comprises colloidal silica.

16. A composition in the form of a tablet comprising

(a) an effective amount of niraparib to inhibit polyadenosine diphosphate ribose polymerase (PARP) when administered to a subject in need thereof;

(b) a first diluent selected from lactose monohydrate, lactose anhydrous, mannitol, and calcium phosphate dibasic;

(c) magnesium stearate;

(d) a second diluent selected from microcrystalline cellulose, starch, polyethylene oxide, and hydroxypropyl methylcellulose (HPMC); and

(e) a binder selected from povidone (PVP), hydroxypropyl cellulose (HPC), and hydroxypropyl methylcellulose (HPMC).

17. The composition of any one of claims 12-16, wherein the first diluent is lactose monohydrate.

18. The composition of any one of claims 12-17, wherein the second diluent is microcrystalline cellulose.

19. The composition of any one of claims 12-18, wherein the binder is povidone (PVP).

20. The composition of any one of claims 12-19, wherein the disintegrant is crospovidone or croscarmellose.

21. The composition of any one of claims 1-20, wherein the composition further comprises silicon dioxide.