

Claims

What is claimed is:

1. A method of making an injectable pharmaceutical composition comprising etanercept, the method comprises:
detecting the presence of one or more particles in the composition,
analyzing the size of the particles and the materials comprised in the particles, and
accepting the injectable pharmaceutical composition if the largest particle of the one or more particles has a length (L) of no more than about 19,200 μm , a width (W) of no more than about 2,939 μm , and a mass (M) of no more than about 97,200 μg ,
wherein the one or more particles comprise acrylic, aluminum, aliphatic hydrocarbon, charcoal, borosilicate glass, wool and silk, polyester (PET), polyurethane, polyether ether ketone, polytetrafluoroethylene (PTFE), polyoxymethylene (POM), polystyrene, silicon carbide, or stainless steel.
2. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 257 μm , a W of no more than about 133 μm , and a M of no more than about 5.4 μg , and the one or more particles comprise acrylic.
3. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 420 μm , a W of no more than about 225 μm , and a M of no more than about 0.001 μg , and the one or more particles comprise aluminum.
4. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 131 μm , a W of no more than about 64 μm , and a M of no more than about 0.42 μg , and the one or more particles comprise aliphatic hydrocarbon.
5. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 176 μm , a W of no more than about 110 μm , and a M of no more than about 2.9 μg , and the one or more particles comprise charcoal.

6. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 5,047 μm , a W of no more than about 2,939 μm , and a M of no more than about 97,200 μg , and the one or more particles comprise borosilicate glass.
7. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 19,200 μm , a W of no more than about 50 μm , and a M of no more than about 50 μg wool and no more than about 50 μg silk, and the one or more particles comprise natural protein fiber (wool and silk).
8. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 2,388 μm , a W of no more than about 67 μm , and a M of no more than about 14.7 μg , and the one or more particles comprise polyester.
9. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 359 μm , a W of no more than about 306 μm , and a M of no more than about 21 μg , and the one or more particles comprise polyurethane.
10. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 5,150 μm , a W of no more than about 300 μm , and a M of no more than about 2,330 μg , and the one or more particles comprise polyether ether ketone.
11. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than about 700 μm , a W of no more than about 250 μm , and a M of no more than about 45.9 μg , and the one or more particles comprise PTFE.
12. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than of about 1,891 μm , a W of no more than about 596.8 μm , and a M of no more than about 1,010 μg , and the one or more particles comprise POM.
13. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than of about 6,154 μm , a W of no more than about 2,454 μm , and a M of no more than about 39,300 μg , and the one or more particles comprise polystyrene.

14. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than of about 359 μm , a W of no more than about 306 μm , and a M of no more than about 48.7 μg , and the one or more particles comprise silicon carbide.
15. The method of claim 1, wherein the largest particle of the one or more particles has a L of no more than of about 450 μm , a W of no more than about 400 μm , and a M of no more than about 72 μg , and the one or more particles comprise stainless steel.
16. The method of claim 1, wherein the injectable pharmaceutical composition is suitable for subcutaneous administration.
17. A method of making an injectable pharmaceutical composition comprising darbepoetin, the method comprises:
detecting the presence of one or more particles in the composition,
analyzing the size of the particles and the materials comprised in the particles, and
accepting the injectable pharmaceutical composition if the largest particle of the one or more particles has a L of no more than about 4,530 μm , a W of no more than about 8,890 μm , and a M of no more than about 21,190 μg ,
wherein the one or more particles comprise acrylate, aluminum, cellulose, epoxy resin, keratin, hydrated aluminum silicate, magnesium, magnesium silicate, nitrocellulose, polyurethane, polytetrafluoroethylene (PTFE), stainless steel, zinc, borosilicate glass, iron, iron and nickel rich material with phosphate, polyamide, polyethylene, polyvinyl chloride (PVC), or titanium.
18. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 302 μm , a W of no more than about 184 μm , and a M of no more than 11 μg , and the one or more particles comprise acrylate.
19. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 74 μm , a W of no more than about 28 μm , and a M of no more than about 0.14 μg , and the one or more particles comprise aluminum.

20. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 479 μm , a W of no more than about 127 μm , and a M of no more than about 11.6 μg , and the one or more particles comprise cellulose.
21. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 442 μm , a W of no more than about 237 μm , and a M of no more than about 60 μg , and the one or more particles comprise epoxy resin.
22. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 2,034 μm , a W of no more than about 1,790 μm , and a M of no more than about 21,190 μg , and the one or more particles comprise borosilicate glass.
23. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 904 μm , a W of no more than about 10 μm , a H of no more than about 412 μm , and a M of no more than about 3 μg iron, no more than about 19.1 μg nickel, and no more than about 6.6 μg phosphate, and the one or more particles comprise iron and nickel rich material with phosphate.
24. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 81 μm , a W of no more than about 44 μm , and a M of no more than about 212 μg , and the one or more particles comprise keratin.
25. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 515 μm , a W of no more than about 509 μm , and a M of no more than about 357.8 μg , and the one or more particles comprise hydrated aluminum silicate.
26. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 836 μm , a W of no more than about 120 μm , and a M of no more than about 1 μg , and the one or more particles comprise magnesium.

27. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 681 μm , a W of no more than about 390 μm , and a M of no more than about 398 μg , and the one or more particles comprise magnesium silicate.
28. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 471 μm , a W of no more than about 333 μm , and a M of no more than about 64.2 μg , and the one or more particles comprise nitrocellulose.
29. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 1,331 μm , a W of no more than about 293 μm , and a M of no more than about 130 μg , and the one or more particles comprise polyamide.
30. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 570 μm , a W of no more than about 321 μm , and a M of no more than about 130 μg , and the one or more particles comprise polyurethane.
31. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 4,530 μm , a W of no more than about 8,890 μm , and a M of no more than about 764 μg , and the one or more particles comprise polyethylene.
32. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 129 μm , a W of no more than about 93 μm , and a M of no more than about 2.4 μg , and the one or more particles comprise PTFE.
33. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 322 μm , and a M of no more than about 181 μg , and the one or more particles comprise PVC.
34. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 254 μm , a W of no more than about 190 μm , and a M of no more than about 72.9 μg , and the one or more particles comprise stainless steel.

35. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 1,331 μm , a W of no more than about 174 μm , and a M of no more than about 926 μg , and the one or more particles comprise titanium.
36. The method of claim 17, wherein the largest particle of the one or more particles has a L of no more than about 836 μm , a W of no more than about 120 μm , and a M of no more than about 4.3 μg , and the one or more particles comprise zinc.
37. The method of claim 17, wherein the pharmaceutical composition is suitable for intravenous or subcutaneous administration.
38. A method of making an injectable pharmaceutical composition comprising pegfilgrastim, the method comprises:
detecting the presence of one or more particles in the composition,
analyzing the size of the particles and the materials comprised in the particles, and
accepting the composition if the largest particle of the one or more particles has a L of no more than about 3,500 μm , a W of no more than about 430 μm , and a M of no more than about 5,100 μg ,
wherein the one or more particles comprise aluminum, calcium carbonate, iron, polytetrafluorocarbon, poly(ethylacrylate), polystyrene, polysulfone, poly(isobutylene)-butyl rubber, rubber, silicate, silicone, or stainless steel.
39. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 209 μm , a W of no more than about 79 μm , and a M of no more than about 0.34 μg , and the one or more particles comprise aluminum silicate.
40. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 931 μm , a W of no more than about 319 μm , and a M of no more than about 278 μg , and the one or more particles comprises calcium carbonate.

41. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 3,547 μm , a W of no more than about 430 μm , and a M of no more than about 5,160 μg , and the one or more particles comprise iron.
42. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 137 μm , a W of no more than about 108 μm , and a M of no more than about 3.5 μg polytetrafluorocarbon and no more than about 1.8 μg poly (ethylacrylate), and the one or more particles comprise polytetrafluorocarbon and poly (ethylacrylate).
43. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 488 μm , a W of no more than about 262 μm , and a M of no more than about 35.5 μg , and the one or more particles comprise polystyrene.
44. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 122 μm , a W of no more than about 105 μm , and a M of no more than about 1.7 μg , and the one or more particles comprises polysulfone.
45. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 209 μm , a W of no more than about 79 μm , and a M of no more than about 1.1 μg , and the one or more particles comprise poly(isobutylene)-buty rubber.
46. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 931 μm , a W of no more than about 319.4 μm , and a M of no more than about 144 μg , and the one or more particles comprise rubber.
47. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 931 μm , a W of no more than about 319 μm , and a M of no more than about 144 μg , and the one or more particles comprise silicate.
48. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 312 μm , and a M of no more than about 54.5 μg , and the one or more particles comprise silicone.

49. The method of claim 38, wherein the largest particle of the one or more particles has a L of no more than about 978 μm , a W of no more than about 166 μm , and a M of no more than about 1246.6 μg , and the one or more particles comprise stainless steel.
50. The method of claim 24, wherein the composition is suitable for subcutaneous administration.