particles. There is a need for developing particle control strategies that take into consideration the impact of particles on patient safety.

Summary

[0004] Provided herein are methods for making injectable pharmaceutical composition by leveraging information of particles historically detected in injectable compositions (e.g., size and materials composition of particles) and the corresponding toxicology and safety evaluations on patients. In one aspect, the present disclosure refers to 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 19,200 μm, a width (W) of no more than 2,939 μm, and a mass (M) of no more than 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. In one example, the disclosure as disclosed herein comprises 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 size and a mass within certain range disclosed herein. In one example, the invention disclosed herein comprises 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, and wherein the one or more particles comprise acrylic, aluminum, aliphatic hydrocarbon, charcoal, borosilicate glass, wool, silk, polyester (PET), polyurethane, polyether ether, polytetrafluoroethylene (PTFE), polyoxymethylene (POM), polystyrene, silicon carbide, or stainless steel.

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 19,200 μm, a width (W) of no more than 2,939 μm, and a mass (M) of no more than 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 257 μm, a W of no more than 133 μm, and a M of no more than 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 420 μm, a W of no more than 225 μm, and a M of no more than 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 131 μm, a W of no more than 64 μm, and a M of no more than 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 176 μm, a W of no more than 110 μm, and a M of no more than 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 5,047 μm, a W of no more than 2,939 μm, and a M of no more than 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 19,200 μm, a W of no more than 50 μm, and a M of no more than 50 μg wool and no more than 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 2,388 μm, a W of no more than 67 μm, and a M of no more than 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 359 μm, a W of no more than 306 μm, and a M of no more than 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 5,150 μm, a W of no more than 300 μm, and a M of no more than 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 700 μm, a W of no more than 250 μm, and a M of no more than 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 1,891 μm, a W of no more than 596.8 μm, and a M of no more than 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 6,154 μm, a W of no more than 2,454 μm, and a M of no more than 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 359 μm, a W of no more than 306 μm, and a M of no more than 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 450 μm, a W of no more than 400 μm, and a M of no more than 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.