

# DRUG INJECTION STOPPER WITH THIN FILM LUBRICANT

## FIELD

[0001] The present disclosure relates generally to an injection device having a low level of lubricant. More specifically, the disclosure relates to injection devices having an elastomeric stopper with a low level of lubricant which interacts with a surface of the stopper and methods for making and using the same.

## BACKGROUND

[0002] Injection devices (e.g., syringes, autoinjectors) used for delivery of drugs include a barrel and a stopper. The stopper is slidably fitted within the barrel and may have a plunger rod affixed to it for actuation of the syringe and delivery of a drug. A liquid lubricant (e.g., silicone oil) is often provided in the injection device to reduce sliding friction between the stopper and the barrel and to improve the seal between them. Pre-filled injection devices may be used as a way to both store and deliver drugs. However, the liquid lubricant present in the injection device may diffuse into the drug contained therein and which may be injected into a patient. Silicone oil may be of particular concern with biopharmaceuticals, because it can cause aggregation of certain proteins, thereby rendering the biopharmaceutical unusable for injection.

## SUMMARY

[0003] According to ~~a one Aspect ("Aspect 1")~~, a syringe includes a barrel configured to hold a therapeutic agent and a plunger rod positioned at least partially within the barrel. The plunger rod includes a stopper having an elastomeric body, a solid lubricant on at least a portion of the exterior of the elastomeric body, and a thin film lubricant positioned between the solid lubricant and an interior of the barrel. A mass of the thin film lubricant on the stopper is from about 0.3  $\mu\text{g}$  to about 100  $\mu\text{g}$ .

[0004] According to ~~one example another Aspect ("Aspect 2") further to Aspect 1~~, the thin film lubricant is silicone and the solid lubricant is a fluoropolymer.

[0005] According to another ~~example Aspect ("Aspect 3"), further to Aspect 1 or Aspect 2~~, the solid lubricant and the thin film lubricant on the stopper represent the total lubricant in the syringe.

[0006] According to another exampleAspect (“Aspect 4”), ~~further to any one of Aspects 1 to 3~~, the stopper is configured to be slidably moved within the barrel with a dry breakaway force less than about 15N.

[0007] According to another one Aspect (“Aspect 5”), a syringe includes a barrel configured to hold a therapeutic agent and a plunger rod positioned at least partially within the barrel, the plunger rod including a stopper. The stopper includes an elastomeric body, a solid lubricant on at least a portion of an exterior of the elastomeric body, and a thin film lubricant positioned between the solid lubricant and an interior of the barrel. The area density of the lubricant on the stopper is about 0.15  $\mu\text{g}/\text{cm}^2$  to about 50  $\mu\text{g}/\text{cm}^2$ .

[0008] According to another exampleAspect (“Aspect 6”), ~~further to Aspect 5~~, the thin film lubricant is silicone and the solid lubricant is a fluoropolymer.

[0009] According to another exampleAspect (“Aspect 7”), ~~further to Aspect 5 or Aspect 6~~, the thin film lubricant reduces an insertion force required to insert the stopper into the barrel by at least about 10%.

[00010] According to another exampleAspect (“Aspect 8”), ~~further to any one of Aspects 5 to 7~~, the thin film lubricant reduces a breakaway force required to move the stopper in the barrel by at least about 10%.

[00011] According to another exampleAspect (“Aspect 9”), ~~further to any one of Aspects 5 to 8~~, the thin film lubricant reduces an average glide force required to move the stopper in the barrel by at least about 2%.

[00012] According to another exampleAspect (“Aspect 10”), ~~further to any one of Aspects 5 to 9~~, an average wet glide force between the stopper and the barrel is less than 5 N.

[00013] According to another exampleAspect (“Aspect 11”), ~~further to any one of Aspects 5 to 10~~, the mass of the thin film lubricant is present in an amount from about 0.3  $\mu\text{g}$  to about 50  $\mu\text{g}$ .

[00014] According to another one Aspect (“Aspect 12”), an injection device includes a barrel configured to hold a therapeutic agent and a plunger rod positioned at least partially within the barrel, the plunger rod including a stopper. The stopper includes an elastomeric body, a solid lubricant on at least a portion of an exterior of the elastomeric body, and a thin film lubricant positioned between the solid lubricant and an interior of the barrel. An average number of particles present in the therapeutic agent with a diameter equal to or greater than 10  $\mu\text{m}$  is about 600 or less, and with a diameter

equal to or greater than 25  $\mu\text{m}$  is about 60 or less.

[00015] According to another ~~exampleAspect (“Aspect 13”), further to Aspect 12,~~ the thin film lubricant is silicone and the solid lubricant is a fluoropolymer.

[00016] According to another ~~exampleAspect (“Aspect 14”), further to Aspect 12 or Aspect 13,~~ the amount of thin film lubricant present on the stopper is from about 0.3 µg to about 100 µg.

[00017] According to ~~another one Aspect (“Aspect 15”),~~ a method for inserting a stopper into a syringe includes lubricating at least one of the stopper, a vent tube, and a barrel with a thin film lubricant, compressing the stopper such that it has a diameter less than a diameter of the vent tube, inserting the stopper into the vent tube, positioning the vent tube at least partially within the barrel, and inserting the stopper into the barrel. The stopper includes between about 0.3 µg and about 100 µg of thin film lubricant once inserted into the barrel.

[00018] According to another ~~exampleAspect (“Aspect 16”), further to Aspect 15,~~ the thin film lubricant is silicone.

[00019] According to another ~~exampleAspect (“Aspect 17”), further to Aspect 15 or Aspect 16,~~ the step of lubrication reduces an insertion force by at least about 5% during at least one of the inserting steps compared to a method without a lubricating step.

[00020] According to another ~~exampleAspect (“Aspect 18”), further to any one of Aspects 15 to 17,~~ including filling at least a portion of the barrel with a therapeutic agent. The average number of particles present in the therapeutic agent does not exceed about 600 with a diameter equal to or greater than 10 µm, and does not exceed about 60 with a diameter equal to or greater than 25 µm.

[00021] According to another ~~exampleAspect (“Aspect 19”), further to any one of Aspects 15 to 18,~~ lubricating includes lubricating the stopper with the thin film lubricant. The thin film lubricant having a surface area density on the stopper is from about 0.15 µg/cm<sup>2</sup> to about 50 µg/cm<sup>2</sup>.

[00022] According to another ~~exampleAspect (“Aspect 20”), further to any one of Aspects 15 to 19,~~ inserting the stopper into the barrel requires an insertion force of less than 30 N.

[00023] The foregoing ~~examplesAspects~~ are just that and should not be read to limit or otherwise narrow the scope of any of the inventive concepts otherwise provided by the instant disclosure. While multiple examples are disclosed, still other ~~examplesembodiments~~ will become apparent to those skilled in the art from the following detailed description, which