The present invention of pre-filled syringe has many benefits compared to a bottle and a separately prepared syringe, such as improved safety, affordability, convenience, accuracy and sterility. The use of pre-filled syringes results in greater dose precision, in a reduction of the potential for needle sticks injuries that can occur while drawing medication from bottles, in pre-measured dosage reducing dosing errors and the risk of contamination due to the need to reconstitute and/or draw medication into a syringe, and in less overfilling of the syringe helping to reduce costs by minimizing drug waste. Moxifloxacin may have advantages as a first-line drug than other fluoroquinolone antibiotic agent, because Moxifloxacin offers boarder spectrum coverage and is available for injection without dilution.

Hence, there is an unmet medical need for Moxifloxacin pre-filled syringes which can safely deliver the drug to the eye and which have the above benefits, but in which the drug is stable for the storage period.

SUMMARY

It has been demonstrated that Moxifloxacin solution retains potency, sterility and stability during storage when filled into a pre-filled polypropylene syringe (Armstrong et al., 2010). The pre-filled syringe of the present disclosure does not contain a significant amount of particles. In one aspect, the present disclosure provides a pre-filled syringe containing a liquid formulation of Moxifloxacin and comprising a syringe barrel, wherein the syringe barrel is preferably made of plastic/glass and is silicone-free.

Moxifloxacin is a fluoroquinolone antibiotic agent, the chemical classification of Moxifloxacin is Quinolones. Moxifloxacin binds to and inhibits the bacterial enzymes DNA gyrase and topoisomerase IV, resulting in inhibition of DNA replication and repair, and cell death in sensitive bacterial species.

In a certain example of the present disclosure, the Moxifloxacin concentration is 0.15 to 500 mg/ml. In one example of the disclosure the pre-filled syringe contains less than 50 particles per ml of the liquid formulation having a diameter of 10 μm or greater.

In another example of the disclosure, the pre-filled syringe contains less than 5 particles per ml of the liquid formulation having a diameter of 25 μm or greater. In still another example of the disclosure, the pre-filled syringe has a gliding force of less than or equal to about 10N.

In a preferred example, the pre-filled syringe further comprises a silicone-free stopper.

Preferably, the syringe barrel is made of cycloolefin polymer or cycloolefin copolymer. In a preferred example the syringe barrel comprises an internal coating other than a silicone coating. Also preferably, the pre-filled syringe comprises a staked needle.

In another aspect, the present disclosure also provides a kit comprising one or more pre-filled syringes as described. Preferably, the kit is a blister pack.

In yet another aspect, the present disclosure refers to the use of a liquid formulation of Moxifloxacin comprising a syringe barrel, wherein the syringe barrel is made of plastic or glass and is silicone-free, in the manufacture of a pre-filled syringe for treating postsurgical endophthalmitis prophylaxis or other related eye diseases and conditions.

In a further aspect, the present disclosure refers to a pre-filled syringe containing a liquid formulation of Moxifloxacin and comprising a syringe barrel, wherein the syringe barrel is made of plastic or glass and is silicone-free, for use as a medical preparation. In yet another aspect, the present disclosure refers to a method of preparing the pre-filled syringe as described herein.

The pre-filled syringe may be used in administering Moxifloxacin intracamerally to a patient post cataract surgery for postsurgical endophthalmitis prophylaxis.

Preferably, a volume of 1 to 500 μL of the liquid formulation is administered to the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows an example of a pre-filled syringe of the present invention for intracameral injection of Moxifloxacin. The pre-filled syringe composes of plunger head, plunger, needle, needle cap, needle guard activation clip, needle guard wings, label, syringe barrel, viewing window, dose marking.

DETAILED DESCRIPTION OF THE INVENTION

The detailed description is merely exemplary in nature and is not intended to limit application and uses. The following examples further illustrate the present invention without, however, limiting the scope of the invention thereto. Various changes and modifications can be made by those skilled in the art on the basis of the description of the invention, and such changes and modifications are also included in the present invention.

Unless indicated otherwise, all ingredient concentrations are presented in units of % weight/volume (% w/v).

Moxifloxacin is preferably present in the compositions of the present invention in the form of a pharmaceutically acceptable salt. Most preferably, moxifloxacin is present in the form of moxifloxacin hydrochloride. The compositions contain moxifloxacin in an amount equivalent to about 0.5% as the free base. The amount of moxifloxacin hydrochloride in the compositions of the present invention is 0.5-0.6%, and is most preferably 0.545%, which is equivalent to 0.5% moxifloxacin as base.

CLAIMS

1. A pre-filled syringe containing a liquid formulation of Moxifloxacin and comprising a syringe barrel, wherein the syringe barrel is made of plastic or glass and is silicone-free.
2. The pre-filled syringe of claim 1, wherein Moxifloxacin is a fluoroquinolone antibiotic agent.
3. The pre-filled syringe of claim 1wherein Moxifloxacin concentration is 0.1 to 500 mg/ml.
4. The pre-filled syringe of claim 1, containing less than 50 particles per ml of the liquid formulation having a diameter of 10 µm or greater.
5. The pre-filled syringe of claim 1, containing less than 5 particles per ml of the liquid formulation having a diameter of 25 µm or greater.
6. The pre-filled syringe of claim 1, having a gliding force of less than or equal to about 10N.
7. The pre-filled syringe of claim 1, further comprising a stopper, preferably a silicone-free stopper.
8. The pre-filled syringe of claim 1, wherein the syringe barrel is made of polymer, such as cycloolefin, or glass.
9. The pre-filled syringe of claim 1, wherein the syringe barrel comprises an internal coating other than a silicone coating.
10. The pre-filled syringe according to claim 1, comprising preferably a staked needle.
11. A kit comprising the pre-filled syringe of claim 1.
12. Use of a liquid formulation of Moxifloxacin comprising a syringe barrel, wherein the syringe barrel is made of plastic or glass and is silicone-free, in the manufacture of a pre-filled syringe for treating postsurgical endophthalmitis prophylaxis or other related eye diseases and conditions.
13. The use of claim 12, wherein the endophthalmitis is an inflammatory condition of intraocular cavity.
14. The use of claim 12, wherein a volume of 1 to 500 µl of the liquid formulation is to be administered to the patient by intracameral injection into the anterior chamber.

15. A pre-filled syringe containing a liquid formulation of Moxifloxacin and comprising a syringe barrel, wherein the syringe barrel is made of plastic or glass and is silicone-free, for use as a medical preparation.

16. A method of preparing the pre-filled syringe of claim 1.