CLAIMS

What is claimed is:

1. Eye drop composition for preventing or treating an ophthalmic disease, characterized in that the eye drop composition comprises:

(a) a lyophilized preparation comprising atropine or a pharmaceutically acceptable salt thereof; and

(b) a reconstitution diluent,

wherein the lyophilized preparation and the reconstitution diluent are separated,

wherein the lyophilized preparation further comprises a buffer salt system, a matrix agent and a stabilizer, and

wherein the reconstitution diluent comprises a buffer salt system, an osmotic pressure regulator, a chelating agent and a bacteriostatic agent.

2. Eye drop composition according to claim 1, characterized in that the pharmaceutically acceptable salt of atropine is atropine sulfate.

3. Eye drop composition according to claim 1, characterized in that a concentration of atropine or the pharmaceutically acceptable salt thereof is in a range from 0.001% to 2%, preferably from 0.01% to 0.5%, or more preferably from 0.01% to 0.08%.

4. Eye drop composition according to claim 1, characterized in that a pH of the eye drop composition is in

a range from 5.0 to 6.4.

5. Eye drop composition according to claim 1, characterized in that the buffer salt system is selected from one or more of a citrate buffer system and a phosphate buffer system, and is preferably the citrate buffer system; and preferably, a concentration of the buffer salt is from 0.01% to 1%.

6. Eye drop composition according to claim 1, characterized in that the matrix agent is selected from one or more of mannitol, sorbitol, sodium chloride and sucrose, and is preferably mannitol; and preferably, a concentration of the matrix agent is from 1% to 4%.

7. Eye drop composition according to claim 1, characterized in that the stabilizer is selected from one or more of sorbitol and mannitol, and is preferably sorbitol; and preferably, a concentration of the stabilizer is from 0.05% to 1%.

8. Eye drop composition according to claim 1, characterized in that the buffer salt system is selected from one or more of purified water, phosphate buffer system and citrate buffer system, and is preferably the citrate buffer system; and preferably, a concentration of the buffer salt is from 0.01% to 1%.

9. Eye drop composition according to claim 1, characterized in that the osmotic pressure regulator is

selected from one or more of mannitol, sodium chloride, glucose, phosphate buffer and borax, and is preferably mannitol; and preferably, a concentration of the osmotic pressure regulator is from 1% to 4%.

10. Eye drop composition according to claim 1, characterized in that the chelating agent is disodium edetate, and preferably, a concentration of the chelating agent is from 0.01% to 0.03%.

11. Eye drop composition according to claim 1, characterized in that the bacteriostatic agent is selected from one or more of benzalkonium chloride, ethylparaben, benzalkonium bromide and polyquaternium-1, and is preferably benzalkonium chloride; and preferably, a concentration of the bacteriostatic agent is from 0.005% to 0.1%.

12. Method for preparing the eye drop composition as defined in any one of claims 1 to 11, characterized in that the method comprises steps of:

(a) contacting the buffer salt system in the lyophilized preparation with atropine or a pharmaceutically acceptable salt thereof, and optionally, one or more of a matrix agent and a stabilizer, and lyophilizing to obtain the lyophilized preparation; and

(b) contacting the buffer salt system in the reconstitution diluent with one or more of an osmotic pressure regulator, a chelating agent and a bacteriostatic

agent optionally to obtain the reconstitution diluent.

13. Method according to claim 12, characterized in that step (a) and step (b) each independently comprise: adjusting the pH of the mixed solution to a range from 5.0 to 6.4 after the contacting is completed.

14. Kit for preventing or treating an ophthalmic disease, characterized in that the kit comprises:

the eye drop composition of any one of claims 1 to 11; and

optionally,

instructions for use.

15. Use of an effective amount of the eye drop composition as defined in any one of claims 1 to 11 characterized in that it is in the preparation of an eye drop for treating an ophthalmic disease, wherein the preparation comprises mixing the lyophilized preparation with the reconstitution diluent.

16. Use according to claim 15, characterized in that the ophthalmic disease is selected from the group consisting of cycloplegia, mydriasis, amblyopia, myopia or a combination thereof, especially myopia in children and adolescents.