PRIOR ART DOCUMENT

PATENT DOCUMENT

[0005]

Patent document 1: JP 2005-336153 A

Patent document 2: JP 2007-99643 A

Patent document 3: JP 2009-46480 A

Patent document 4: JP 2011-93888 A

Patent document 5: JP 2011-213729 A

Patent document 6: JP 2014-5417 A

Patent document 7: JP 2015-78248 A

Patent document 8: JP 2017-178880 A

SUMMARY

PROBLEMS TO BE SOLVED BY THE DISCLOSURE

[0006]

The objective of the present disclosure is to provide a pharmaceutical composition excellent in storage stability.

MEANS FOR SOLVING THE PROBLEMS

[0007]

The inventor of the present disclosure made extensive studies. As a result, the inventor found that while a residual ratio of glucose in a pharmaceutical composition having a low concentration of glucose is decreased with time, a non-ionic surfactant is very effective in stabilizing glucose. The inventor completed the present disclosure by finding that a pharmaceutical composition mixed with a non-ionic surfactant becomes cloudy during storage but such white turbidity can be suppressed by mixing an alkyldiaminoethylglycine

hydrochloride.

Hereinafter, the embodiment of the present disclosure is described.

[0008]

[1] In one aspect, there is provided a pharmaceutical composition comprising 0.0005 w/v% or more and 0.05 w/v% or less of glucose, a non-ionic surfactant and an alkyldiaminoethylglycine hydrochloride.

[2] The pharmaceutical composition according to the above [1], comprising 0.0005 w/v% or more and 0.01 w/v% or less of the glucose.

[3] The pharmaceutical composition according to the above [1] or [2], comprising 0.002 w/v% or more and 0.01 w/v% or less of the glucose.

[4] The pharmaceutical composition according to any one of the above [1] to [3], wherein the non-ionic surfactant is one or more non-ionic surfactants selected from the group consisting of polyoxyethylene hydrogenated castor oil, polyoxyethylene sorbitan long-chain fatty acid monoester, polyethylene glycol long-chain fatty acid monoester and polyoxyethylene-polyoxypropylene block copolymer.

[5] The pharmaceutical composition according to any one of the above [1] to [4], comprising 0.001 w/v% or more and 0.5 w/v% or less of the non-ionic surfactant.

[6] The pharmaceutical composition according to any one of the above [1] to [4], wherein a concentration of the non-ionic surfactant is 0.005 w/v% or more and 0.3 w/v% or less.

[7] The pharmaceutical composition according to the above [4], wherein the polyoxyethylene hydrogenated castor oil is polyoxyethylene hydrogenated castor oil 60.

[8] The pharmaceutical composition according to any one of

agent,

wherein pH is 6.5 or more and 8.0 or less.

[44] In another aspect, there is provided a pharmaceutical composition comprising:

0.005 w/v% of glucose,

0.01 w/v% of a non-ionic surfactant, and

0.0025 w/v% of an alkyldiaminoethylglycine hydrochloride.

[45] The pharmaceutical composition according to any one of the above [1] to [44], wherein the pharmaceutical composition is ophthalmic.

[46] The pharmaceutical composition according to any one of the above [1] to [45], wherein the pharmaceutical composition is an aqueous liquid composition.

[47] The pharmaceutical composition according to any one of the above [1] to [46], wherein the pharmaceutical composition is an ophthalmic solution.

[48] Use of 0.0005 w/v% or more and 0.05 w/v% or less of glucose, a non-ionic surfactant and an alkyldiaminoethylglycine hydrochloride for improving storage of a pharmaceutical composition.

[49] Use of 0.0005 w/v% or more and 0.05 w/v% or less of glucose, a non-ionic surfactant and an alkyldiaminoethylglycine hydrochloride for producing a pharmaceutical composition excellent in storage stability.

[50] A method for improving storage stability of a pharmaceutical composition,

wherein the pharmaceutical composition comprises 0.0005 w/v% or more and 0.01 w/v% or less of glucose,

the method comprising the step of mixing a non-ionic surfactant and an alkyldiaminoethylglycine hydrochloride in the pharmaceutical composition.

The matters specified in the above [1] to [47] can be applied to the above-described use and method.

EFFECT OF THE DISCLOSURE

[0009]

The pharmaceutical composition of the present disclosure is excellent in storage stability.

MODE FOR CARRYING OUT THE INVENTION

[0010]

Various ophthalmic pharmaceutical compositions to complement tears have been developed as described above, and the glucose concentration in an ophthalmic pharmaceutical composition is generally adjusted to be higher than the concentration in actual tears.

[0011]

The present inventor found that when the glucose concentration in a composition is adjusted to be low similarly to the concentration in tears, the glucose concentration cannot be maintained during storage. Thus, the present inventor investigated a component to stabilize glucose and found that a non-ionic surfactant is effective. On the one hand, the present inventor found that when a non-ionic surfactant is mixed in a composition containing low concentration glucose, the composition becomes cloudy during storage. The present inventor investigated a component to prevent such white turbidity; and as a result, found that an alkyldiaminoethylglycine hydrochloride is effective.

[0012]

The pharmaceutical composition of the present invention