

CLAIMS

1.- An ophthalmic pharmaceutical composition comprising:

- a peptide or a pharmaceutically acceptable salt or solvate thereof with a sequence length from 13 to 50 amino acids, the N-terminal region of said peptide consisting of the sequence:

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HXaa¹EGTFTSDXaa²SXaa³Xaa⁴(SEQ ID NO: 1) wherein:

Xaa¹ is an amino acid selected from alanine and glycine;

Xaa² is an amino acid selected from valine and leucine;

Xaa³ is an amino acid selected from serine and lysine;

10 Xaa⁴ is an amino acid selected from tyrosine and glutamine; and

histidine is the N-terminal residue; and

- one or more pharmaceutically acceptable excipients or carriers;

wherein the pH value of the composition is between 4.0 and 4.8 and the osmolality ranges between 0.5 and 200 mOsm/kg.

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2.- The ophthalmic pharmaceutical composition according to the preceding claim, wherein the sequence length is from 30 to 40 amino acids.

3.- The ophthalmic pharmaceutical composition according to any one of the preceding claims, wherein

20 Xaa¹ is alanine, Xaa² is valine, Xaa³ is serine, and Xaa⁴ is tyrosine.

4.- The ophthalmic pharmaceutical composition according to any one of the preceding claims, wherein the peptide is a mammal glucagon-like peptide-1, or a pharmaceutically acceptable salt thereof.

25 5.- The ophthalmic pharmaceutical composition according to any one of the preceding claims, wherein the peptide is:

(a) a peptide comprising or consisting of the amino acid sequence SEQ ID NO: 2 or a pharmaceutically acceptable salt thereof; or, alternatively,

30 (b) a peptide with an amino acid sequence having at least 85% of identity degree with SEQ ID NO: 2 or a pharmaceutically acceptable salt thereof, provided that the N-terminal region is as defined in claim 1, or, alternatively,

(c) a peptide with a sequence length up to 50 amino acids comprising an amino acid sequence having at least 85% of identity degree with SEQ ID NO: 2 or a pharmaceutically acceptable salt thereof, provided that the N-terminal region is as defined in claim 1; or, alternatively,

35 (d) a fragment of a peptide having at least 85% of identity degree with SEQ ID NO: 2 or a

pharmaceutically acceptable salt thereof, provided that the fragment has an amino acid length from 14 to 49 amino acids and includes the N-terminal region as defined in claim 1.

5 6.- The ophthalmic pharmaceutical composition according to any one of the claims 1 to 5, wherein the peptide is a pharmaceutically acceptable salt of the sequence SEQ ID NO: 2, particularly an acetate salt of the sequence SEQ ID NO: 2; or, alternatively, the peptide is the sequence SEQ ID NO: 2.

7.- The ophthalmic pharmaceutical composition according to any one of the preceding claims, wherein the pH value is between 4.1 and 4.8.

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8.- The ophthalmic pharmaceutical composition according to any one of the preceding claims, wherein the osmolality ranges from 1 to 150 mOsm/kg.

9.- The ophthalmic pharmaceutical composition according to any one of the preceding claims, wherein at least one of the one or more pharmaceutically acceptable excipients or carriers is selected from the group consisting of a stabilizing agent, a viscosifying agent, a buffering agent and mixtures thereof.

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10.- The ophthalmic pharmaceutical composition according to the preceding claim 9, wherein the stabilizing agent is aspartic acid or glutamic acid.

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11.- The ophthalmic pharmaceutical composition according to any one of the preceding claims further comprising an effective amount of a preservative.

12.- The ophthalmic pharmaceutical composition according to the preceding claim, wherein the preservative is selected from edetate sodium, benzalkonium chloride, centrimonium chloride, sodium perborate, stabilized oxychloro complex, sorbic acid, thimerosal, polyquarternium-1, polyhexamethylene biguanide, chlorobutanol, phenylethyl alcohol, methylparaben, propylparaben, a combination of boric acid, sorbic acid, and propylene glycol; and mixtures thereof, preferably the preservative is benzalkonium chloride.

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13. A lyophilizate comprising the peptide as defined in any one of the claims 1 to 6 or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable amount of a stabilizing agent and/or buffering agent. wherein said lyophilizate is suitable for preparing the ophthalmic pharmaceutical composition according to any one of the preceding claims by reconstitution.

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14. A process for preparing the ophthalmic pharmaceutical composition according to any one of the

claims 1 to 12, which comprises the step of reconstituting the lyophilizate as defined in claim 13 with an aqueous vehicle composition comprising one or more pharmaceutically acceptable carriers or excipients, particularly an aqueous vehicle composition comprising at least one viscosifying agent and optionally at least one preservative.

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15. An ophthalmic pharmaceutical composition according to any one of claims 1 to 12 for use in the topical eye treatment and/or prevention of a retinal neurodegenerative disease.

16. A kit comprising the lyophilizate as defined in claim 13 and a physiologically acceptable vehicle composition comprising one or more pharmaceutically acceptable excipients or carriers, for reconstituting the peptide.

17. A kit comprising the ophthalmic pharmaceutical composition as defined in any of the claims 1-12, a container for holding the pharmaceutical composition and a drop dispenser adapted for administering a volume of the composition.

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