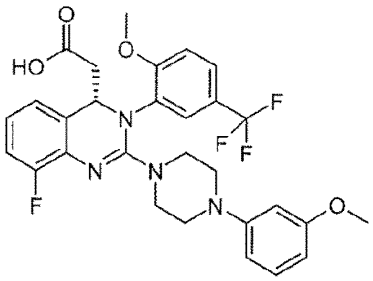
Claims

1. A pharmaceutical composition comprising letermovir of formula (I), and sodium ions



(I)

wherein the pharmaceutical composition

- comprises the sodium ions in a molar ratio to letermovir in the range of from 0.50 to < 1.00 : 1.00, preferably of from 0.65 to < 1.00 : 1.00, more preferably of from 0.72 to < 1.00 : 1.00, more preferably of from 0.80 to < 1.00 : 1.00, more preferably of from 0.80 to 0.90 : 1.00; and
- is capable of exhibiting a pH in the range of from 7 to 8, preferably 7.4 to 7.8, when said pharmaceutical composition is dissolved in water in a concentration range of from 20 to 100 mg/mL with respect to letermovir; and
- is essentially free from complexing solubilizing agents selected from the group consisting of PEG, lysine, arginine, a cyclodextrin, in particular a hydroxypropyl-beta-cyclodextrin (HPBCD).

2. The pharmaceutical composition according to claim 1, further comprising at least one excipient selected from the group consisting of a carbohydrate, in particular selected from sucrose and mannitol, an amino acid, in particular phenylalanine, a polyalkoxy compound, in particular a poloxamer, more particular poloxamer 188, and a polyvinylpyrrolidone (PVP), in particular PVP PF12.

3. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is essentially free from complexing solubilizing agents.

4. The pharmaceutical composition according to any one of claims 1 or 2, wherein the pharmaceutical composition comprises a polyalkoxy compound, in particular a

poloxamer, more particular poloxamer 188, and is essentially free from other complexing solubilizing agents.

5. The pharmaceutical composition according to claim 2, wherein the excipient is mannitol or sucrose or a combination thereof.

6. The pharmaceutical composition according to any one of claims 1 to 5, further comprising a buffer, preferably Tris hydroxy aminomethane (Tris).

7. A method of producing the pharmaceutical composition as defined in any one of claims 1 to 6, comprising the following steps:

i) providing a solution of letermovir and sodium ions, wherein the molar ratio of sodium ions to letermovir is in the range of from 0.50 to < 1.00 : 1.00, preferably of from 0.65 to < 1.00 : 1.00, more preferably of from 0.72 to < 1.00 : 1.00, more preferably of from 0.80 to < 1.00 : 1.00, more preferably of from 0.80 to 0.90 : 1.00, and optionally at least one excipient selected from the group consisting of a carbohydrate, in particular sucrose or mannitol, an amino acid, in particular phenylalanine, a polyalkoxy compound, in particular a poloxamer, more particular poloxamer 188, and a polyvinylpyrrolidone (PVP), in particular PVP PF12

ii) if needed adjusting the pH of the solution obtained in step i) to a range of from 7 to 8, preferably from 7.4 to 7.8, preferably with HCl

iii) optionally filtering said solution.

8. The method according to claim 7, further comprising the subsequent additional step of freeze-drying the obtained solution to provide a lyophilizate.

9. The method according to claim 8, further comprising the subsequent additional step of reconstituting the lyophilizate in a first parenterally acceptable diluent to provide a reconstituted solution in a concentration range of from 20 to 100 mg/mL with respect to letermovir and optionally subsequently diluting said reconstituted solution with a second parenterally acceptable diluent to a final concentration which is acceptable for injection or infusion, wherein said first and said second parenterally acceptable diluents can be the same or different.

10. The pharmaceutical composition according to any one of claims 1 to 6, which is obtainable by the method as defined in any one of claims 7 to 9.

11. The pharmaceutical composition according to any one of claims 1 to 6 or 10 for use in a method of treatment and/or prevention of diseases, in particular of virus infections, preferably human cytomegalovirus (HCMV) infections or infections with another member of the herpes viridae group.

12. The use of a pharmaceutical composition according to any one of claims 1 to 6 or 10 for the preparation of a medicament for the treatment and/or prevention of diseases, in particular of virus infections, preferably human cytomegalovirus (HCMV) infections or infections with another member of the herpes viridae group.

13. A method of treatment and/or prevention of virus infections, preferably human cytomegalovirus (HCMV) infections or infections with another member of the herpes viridae group, in a subject in need thereof wherein the method comprises administering the pharmaceutical composition as defined in any one of claims 1 to 6 or 10.