Claims

1. A fosphenytoin sodium solid composition, comprising fosphenytoin sodium and at least one carbohydrate, wherein, prior to lyophilization, the weight-to-volume ratio of the carbohydrate in the composition is 5% to 10%, and the solid composition is a lyophilized composition.

2. The fosphenytoin sodium solid composition according to claim 1, wherein the solid composition can be stored at room temperature.

3. The fosphenytoin sodium solid composition according to claim 1 or 2, wherein the carbohydrate is at least one selected from sugar and oligosaccharide;

preferably, the sugar is at least one selected from monosaccharide, disaccharide and sugar alcohol;

preferably, the monosaccharide is at least one selected from glucose, galactose and fructose;

preferably, the disaccharide is at least one selected from sucrose, lactose, trehalose, maltose and isomaltose;

preferably, the sugar alcohol is at least one selected from sorbitol, mannitol, xylitol and maltitol; and

preferably, the oligosaccharide is at least one selected from raffinose, stachyose, isomaltooligosaccharide, fructooligosaccharide, mannose oligosaccharide and soybean oligosaccharide.

4. The fosphenytoin sodium solid composition according to any one of claims 1 to 3, wherein the solid composition further comprises a buffer.

5. The fosphenytoin sodium solid composition according to claim 4, wherein the buffer is one or more selected from phosphate buffer, hydrophosphate buffer, dihydrogen phosphate buffer, bicarbonate buffer, carbonate buffer, boric acid buffer, borate buffer, amino acid buffer, trialkylamine buffer, tromethamine buffer, pyrophosphate buffer, Glycyl Glycine (glycylglycine) buffer; preferably, the phosphate, hydrophosphate, dihydrogen phosphate, bicarbonate, carbonate, borate and pyrophosphate are independently a sodium salt and/or a potassium salt; the trialkylamine is trimethylamine; preferably, prior to lyophilization, a concentration of the buffer is 10 to 150 mM, and more preferably 20 to 100 mM.

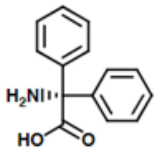
6. The fosphenytoin sodium solid composition according to any one of claims 1 to 5, wherein the pH of the fosphenytoin sodium solid composition prior to lyophilization or after

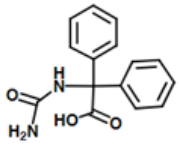
reconstitution is 8 to 10, preferably 8 to 9.3, and more preferably 8 to 9.

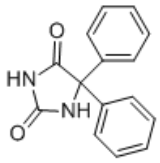
7. The fosphenytoin sodium solid composition according to any one of claims 1 to 6, wherein, prior to lyophilization, the concentration of the fosphenytoin sodium is 75 mg/mL to 150 mg/mL, preferably 75 mg/mL to 100 mg/mL; and more preferably 75 mg/mL or 100 mg/mL.

8. The fosphenytoin sodium solid composition according to any one of claims 1 to 7, wherein, after reconstitution, the concentration of the fosphenytoin sodium is 75 mg/mL to 150 mg/mL, preferably 75 mg/mL to 100 mg/mL; and more preferably 75 mg/mL.

9. The fosphenytoin sodium solid composition according to any one of claims 1 to 8, wherein no Impurity A, Impurity B or Impurity C is generated in the fosphenytoin sodium solid composition after being placed at 25°C and 60% relative humidity for 14 days; preferably, no Impurity A, Impurity B or Impurity C is generated in the fosphenytoin sodium solid composition after being placed at 25°C and 60% relative humidity for 3 months,

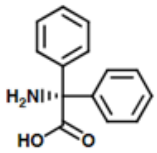


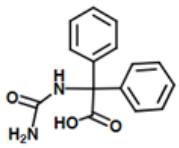


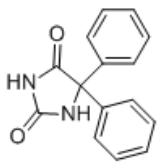


Impurity A Impurity B Impurity C.

10. The fosphenytoin sodium solid composition according to any one of claims 1 to 8, wherein no Impurity A, Impurity B or Impurity C is generated in the fosphenytoin sodium solid composition after being placed at 40°C and 75% relative humidity for 14 days; preferably, no Impurity A, Impurity B or Impurity C is generated in the fosphenytoin sodium solid composition after being placed at 40°C and 75% relative humidity for 3 months,







Impurity A Impurity B Impurity C.

11. The fosphenytoin sodium solid composition according to any one of claims 1 to 10, wherein the solid composition is a lyophilized composition comprising fosphenytoin sodium, a buffer and at least one carbohydrate; the buffer is tromethamine; the carbohydrate is selected from trehalose, sucrose, mannitol or lactose; and the pH of the lyophilized composition before

lyophilization or after reconstitution is 8 to 9;

preferably, prior to lyophilization, the concentration of the fosphenytoin sodium is 75 mg/mL or 100 mg/mL, the concentration of the buffer is 20 to 100 mM, and the weight-to-volume ratio of the carbohydrate in the composition is 5% to 10 %.

12. A lyophilization method of fosphenytoin sodium solid composition according to any one of claims 1 to 11, including: (1) preparing a fosphenytoin sodium solution; (2) pre-freezing the fosphenytoin sodium solution; and (3) directly increasing the shelf temperature at a certain heating rate to a predetermined temperature for drying, rather than individually setting a sublimation drying step and an analytical drying step,

wherein the total lyophilization time of the lyophilization method is reduced by more than 60% relative to a total lyophilization time of conventional lyophilization methods.

13. The lyophilization method of fosphenytoin sodium according to claim 12, wherein the pre-freezing temperature in Step (2) is -40°C to -60°C, preferably -45°C to -55°C, and more preferably -45°C to -50°C; preferably, the cooling rate of decreasing the temperature to the pre-freezing temperature is 0.5 to 6 °C/min, preferably 1 to 5 °C/min, and more preferably 1 to 1.5 °C/min; preferably, the heating rate in Step (3) is 0.01 to 5 °C/min, preferably 0.025 to 3 °C/min, and more preferably 0.05 to 1.5 °C/min; preferably, the shelf temperature is directly increased to 5°C to 25°C, preferably to 10°C to 25°C, and more preferably to 20°C to 25°C;

preferably the total lyophilization time of the lyophilization method is reduced by more than 70% relative to a total lyophilization time of conventional lyophilization methods.

14. Use of the fosphenytoin sodium solid composition according to any one of claims 1 to 11 in preparation of a medicament for treatment of epilepsy or other convulsive states.