Claims

1. A ginkgolide injection, characterized in that the injection comprises the following components:

1 - 10mg/ml of ginkgolide (counted based on terpene lactone);

0.2 - 0.5ml/ml of glycerol;

0.4 - 0.7ml/ml of ethanol; and

0 - 0.5ml/ml of water for injection.

2. The ginkgolide injection of claim 1, characterized in that the injection comprises the following components:

5mg/ml of ginkgolide (counted based on terpene lactone);

0.4ml/ml of glycerol; and

0.6ml/ml of ethanol.

3. The ginkgolide injection of claim 1, characterized in that the injection comprises the following components:

5mg/ml of ginkgolide (counted based on terpene lactone);

0.2ml/ml of glycerol;

0.6ml/ml of ethanol; and

0.2ml/ml of water for injection.

4. The ginkgolide injection of claim 1, characterized in that the volume ratio of the ethanol and the glycerol is 1 - 5:1 by parts.

5. The ginkgolide injection of any of claims 1 to 4, characterized in that the ginkgolide contains 25.0 - 50.0% of bilobalide, 20.0 - 45.0% of ginkgolide A, 10.0 - 30.0% of ginkgolide B and 5.0 - 15.0% of ginkgolide C counted on a dry basis; and the total amount of the bilobalide, the ginkgolide A, the ginkgolide B and the ginkgolide C is not less than 95.0%.

6. A preparation method of the ginkgolide injection of claim 1, characterized in that the injection is prepared from the following components:

1 - 10mg/ml of ginkgolide (counted based on terpene lactone);

0.2 - 0.5ml/ml of glycerol;

0.4 - 0.7ml/ml of ethanol; and

0 - 0.5ml/ml of water for injection;

by the following steps:

a) preparation: mixing the ethanol and the glycerol, adding the ginkgolide for dissolving, adding the ethanol or the water for injection to full volume, and adjusting pH value to 2.5 - 6.5 with 5 - 10% citric acid solution or 1 - 10% hydrochloric acid solution;

b) filtration for sterilization;

c) filling and sealing; and

d) sterilization.

7. The preparation method of the ginkgolide injection of claim 6, characterized in that the pH value is adjusted to 3.2 – 3.8 in the step a) preparation.

8. The preparation method of the ginkgolide injection of claim 6 or 7, characterized in that the volume ratio of the ethanol and the glycerol is 1 - 5:1 by parts in the step a) preparation.

Claims

1. A ginkgolide injection, characterized in that the injection comprises the following components:

   1 - 10mg/ml of ginkgolid: (counted based on terpene lactone);

   0.2 - 0.5ml/ml of glycerol;

   0.4 - 0.7 ml/ml of ethanol; and

   0 - 0.5 ml/ml of water for injection; and

   a preparation method of the injection comprises the following steps:

   a) preparation: mixing the ethanol and the glycerol, adding the ginkgolide for dissolution, adding the ethanol or the water for injection to full capacity, and adjusting pH value to 2.5 - 6.5 with 5 - 10% citric acid solution or 1 - 10% hydrochloric acid solution;

   b) filtration for sterilization;

   c) filling and sealing; and

   d) sterilization.

2. The ginkgolide injection of claim 1, characterized in that the injection comprises the following components:

   5mg/ml of ginkgolide (counted based on terpene lactone);

   0.4ml/ml of glycerol ; and

   0.6ml/ml of ethanol.

3. The ginkgolide injection of claim 1, characterized in that the volume ratio of the ethanol to the glycerol is 1 - 5:1 by parts.

4. The ginkgolide injection of claim 1, characterized in that the pH value is adjusted to 3.2 – 3.8 in step a) preparation.

5. The ginkgolide injection of any of claims 1 to 4, characterized in that the ginkgolide contains 25.0 - 50.0% of bilobalide, 20.0 - 45.0% of ginkgolide A, 10.0 - 30.0% of ginkgolide B and 5.0 - 15.0% of ginkgolide C on a dry basis; and the total amount of the bilobalide, the ginkgolide A, the ginkgolide B and the ginkgolide C is not less than 95.0%.

6. A quality control method for the ginkgolide injection of any of claims 1 to 5, characterized by comprising the following items:

   character: colorless clear liquid;

   pH value: 3.0 - 4.5;

   tannin, resin, oxalate, potassium ion: not detected;

   undue toxicity: the injection is prepared into a solution containing 0.2mg per 1ml, and the solution conforms to administration by intravenous injection;

   allergic test: to the injection 0.9% sodium chloride injection is added to dilute to 0.4mg/ml counted based on terpene lactone, and allergic reaction should be not present within 30min after intravenous injection of the test solution;

   total ginkgolic acid: total content of ginkgolic acid is not more 1ppm by external standard method for ginkgolic acid control when chromatographic column is C18, mobile phase is methanol:1% glacial acetic acid (90:10), detection wavelength is 310nm;

   fingerprint: the similarity of four common peaks and the reference fingerprint is determined more than 0.95 by HPLC based on the similarity evaluation system for chromatographic fingerprints of traditional Chinese medicines using bilobalide control, ginkgolide A control, ginkgolide B control and ginkgolide C control as references; and

   content: the content of terpene lactone per 1ml is determined to be 4.5 - 5.5mg by HPLC based on total amount of the bilobalide ($C_{15}H_{18}O_8$), the ginkgolide A ($C_{20}H_{24}O_9$), the ginkgolide B ($C_{20}H_{24}O_{10}$) and the ginkgolide C ($C_{20}H_{24}O_{11}$).