CLAIMS

What is claimed is:

1. A 5α-androstane-3β,5,6β-triol injection, including a liquid injection having a solvent or a solid injection, comprises at least one soluble excipient, wherein the at least one soluble excipient includes hydroxypropyl-β-cyclodextrin.

2. The injection of claim 1, wherein the 5α-androstane-3β,5,6β-triol is present at a part by weight ratio of 1~20: 40~500 to hydroxypropyl-β-cyclodextrin.

3. The injection of claim 1 or 2, wherein the soluble excipient further comprises an isotonic adjusting agent and/or a freeze drying filler.

4. The injection of claim 3, wherein the isotonic adjusting agent is selected from the group consisting of sodium chloride, glucose, mannitol, lactose, xylitol, sorbitol, maltitol and mixtures thereof.

5. The injection of claim 3, wherein the freeze-drying filler is selected from the group consisting of sodium chloride, glucose, mannitol, lactose, xylitol, sorbitol, maltitol and mixtures thereof.

6. The injection of claim 1 or 2, wherein the solvent of the liquid injection is selected from the group consisting of propanediol, ethanol, polyethylene glycol 400, polyethylene glycol 200, glycerol, water and mixtures thereof.

7. The injection of claim 3, wherein the injection is consisted of (by weight): 1~20 parts of 5α-androstane-3β,5,6β-triol, 4~500 parts of hydroxypropyl-β-cyclodextrin, 1~100 parts of an isotonic adjusting agent, 0~200 parts of a freeze drying filler, and 0~2000 parts of a solvent.

8. A method for preparing the injection of claim 1, comprising steps of

(a) dissolving hydroxypropyl-β-cyclodextrin, 5α-androstane-3β, 5,6β-triol and addtional soluble excipients in water for injection in sequence to obtain a raw injection solution, and

(b1) subjecting the raw injection solution to decolorization, depyrogenation, filtration and sterilization to obtain the injection, or

(b2) subjecting the raw injection solution to decolorization, depyrogenation, filtration and filling a filtrate produced by the filtration into an ampoule, followed by freeze drying to obtain the freeze drying powder, or

(b3) subjecting the raw injection solution to decolorization, depyrogenation, filtration and spray drying a filtrate produced by the filtration, followed by packaging.

9. The method of claim 8, wherein the decolorization is achieved by using

activated charcoal at an amount of 0.05~0.3 wt% of the injection.

10. The method of claim 8 or 9, wherein the sterilization is performed at 115°C for 30 min or at 121°C for 15 min.

CLAIMS

1. An injectable composition in the form of a liquid having a solvent or in the form of a solid, the injectable composition comprising: 5α-androstane-3β,5,6β-triol and at least one soluble excipient, wherein the at least one soluble excipient includes hydroxypropyl-β-cyclodextrin.

2. The injectable composition of claim 1, wherein the weight ratio of 5α-androstane-3β,5,6β-triol to hydroxypropyl-β-cyclodextrin is 1-20: 40-500.

3. The injectable composition of claim 1 or claim 2, wherein the soluble excipient further comprises an isotonic adjusting agent and/or a freeze drying filler.

4. The injectable composition of claim 3, wherein the isotonic adjusting agent is selected from the group consisting of: sodium chloride, glucose, mannitol, lactose, xylitol, sorbitol, maltitol and mixtures thereof.

5. The injectable composition of claim 3, wherein the freeze-drying filler is selected from the group consisting of: sodium chloride, glucose, mannitol, lactose, xylitol, sorbitol, maltitol and mixtures thereof.

6. The injectable composition according to any one of claims 1 to 5, wherein the solvent is selected from the group consisting of: propanediol, ethanol, polyethylene glycol 400, polyethylene glycol 200, glycerol, water and mixtures thereof.

7. The injectable composition according to any one of claims 3 to 5, wherein the injectable composition consists of (by weight): 1-20 parts of the 5α-androstane-3β,5,6β-triol, 4-500 parts of the hydroxypropyl-β-cyclodextrin, 1-100 parts of the isotonic adjusting agent, 0-200 parts of the freeze drying filler, and 0-2000 parts of the solvent.

8. A method for preparing the injectable composition of claim 1, comprising steps of:

(a) dissolving hydroxypropyl-β-cyclodextrin, 5α-androstane-3β, 5,6β-triol and additional soluble excipients in water for injection in sequence to obtain a raw injectable solution; and

(b1) subjecting the raw injectable solution to decolorization, depyrogenation, filtration and sterilization to obtain the injectable composition; or

(b2) subjecting the raw injectable solution to decolorization, depyrogenation, filtration and filling a filtrate produced by the filtration into an ampoule, followed by freeze drying to obtain a freeze dried powder; or

(b3) subjecting the raw injectable solution to decolorization, depyrogenation, filtration and spray drying a filtrate produced by the filtration to produce a powder,

and packaging the powder.

9. The method of claim 8, wherein the decolorization is achieved by using activated charcoal at an amount of 0.05-0.3 wt% of the injectable composition.

10. The method of claim 8 or claim 9, wherein the sterilization is performed at 115 °C for 30 min.

11. The method of claim 8 or claim 9, wherein the sterilization is performed at 121 °C for 15 min.