5α-ANDROSTANE-3β,5,6β-TRIOL INJECTION AND PREPARATION METHOD THEREFOR

ABSTRACT

A 5α-androstane-3β,5,6β-triol injection and its preparation are disclosed. The injection uses hydroxypropyl-β-cyclodextrin as a solubilizing agent and the active ingredient is present in a part by weight ratio of 1~20:40~500 to the hydroxypropyl-β-cyclodextrin. The injection may also comprise 1~100 parts of an isotonic adjusting agent, 0~200 parts of a freeze drying filler, and 0~2000 parts of a solvent. The preparation method comprises dissolving hydroxypropyl-β-cyclodextrin solution, 5α-androstane-3β,5,6β-triol and soluble excipients in water for injection in sequence to obtain a raw injection solution, and subjecting the raw injection solution to decolorization, depyrogenation, filtration and sterilization to obtain the injection. Drying the filtrate yields a solid for injection.