Patent Claims

1. Pharmaceutical solution having a pH of 10 or higher, containing telmisartan~~an angiotensin II receptor antagonist~~, characterised in that one or more sugar alcohols are present up to a total concentration of 40 wt.% to 70 wt.%, preferably 60 wt.% to 70 wt.%, wherein the sugar alcohol or alcohols have a maximum content of 1000 ppm of reducing sugar before they are added to the solution.

2. The pharmaceutical solution according to claim 1, characterised in that the solution is a drinkable solution.

~~3. The pharmaceutical solution according to claim 1 or 2, characterised in that the angiotensin II receptor antagonist is telmisartan.~~

4~~3~~. The pharmaceutical solution according to ~~one of~~ claims ~~1 to 3~~or 2, characterised in that the pharmaceutical solution has a maximum content of 1000 ppm of reducing sugars.

5~~4~~. The pharmaceutical solution according to one of claims 1 to 4~~3~~, characterised in that the pharmaceutical solution has a minimum content of 250 ppm of reducing sugars.

6~~5~~. The pharmaceutical solution according to one of claims 1 to 5~~4~~, characterised in that the pH is obtained by the presence of meglumine, sodium hydroxide, potassium hydroxide, or a basic amino acid such as arginine or glutamine.

7~~6~~. The pharmaceutical solution according to one of claims 1 to 6~~5~~, characterised in that ~~the angiotensin II receptor antagonist, preferably~~ telmisartan~~,~~ is present in a concentration of 1 to 10 mg/ml, preferably 1 to 5 mg/ml.

8~~7~~. The pharmaceutical solution according to one of claims 1 to 7~~6~~, characterised in that the proportion of reducing sugars in the solution based on the quantity of active substance of the telmisartan ~~angiotensin II receptor antagonist~~ is less than 20 % by weight.

9~~8~~. The pharmaceutical solution according to one of claims 1 to 8~~7~~, characterised in that the sugar alcohol or alcohols are selected from among xylitol, maltitol, sorbitol, mannitol, erythritol and isomaltol.

~~10~~9. The pharmaceutical solution according to one of claims 1 to ~~9~~8, characterised in that it optionally contains other formulation adjuvants.

~~11~~10. The pharmaceutical solution according to one of claims 1 to ~~10~~9, characterised in that o-cresol, m-cresol, p-cresol or benzalkonium chloride are added as preservatives, optionally alone or in combination.

~~12~~11. The pharmaceutical solution according to one of claims 1 to ~~11~~10, characterised in that it is substantially free, preferably free from antioxidants or stabilisers.

~~13~~12. The pharmaceutical solution according to one of claims 1 to ~~12~~11 for treating hypertension or kidney disease in people, particularly children, old people or people having difficulty swallowing; or in animals, particularly dogs and cats.

~~14~~13. Method of preparing a pharmaceutical solution according to one of claims 1 to ~~12~~11, characterised by

a) dissolving ~~the angiotensin-II-receptor antagonist, preferably~~ telmisartan~~,~~ and a sugar alcohol having a content of reducing sugars of less than 1000 ppm, preferably less than 300 ppm, in an excess of a pharmaceutically acceptable base until a pH of at least 10 or higher is obtained; and

b) adjusting the concentration of ~~the angiotensin-II-receptor antagonist, preferably~~ telmisartan~~,~~ to 1 to 10 mg/ml.

~~15~~14. Method according to claim ~~14~~13 comprising the steps of:

a) swelling a consistency-producing agent with purified water;

b) dissolving the swollen consistency-producing agent at a temperature of ≥ 50°C;

c) adding a pharmaceutically acceptable base at a temperature of ≥ 50°C until a pH of ≥ 10.0 is obtained;

d) adding and dissolving the ~~angiotensin-II-receptor antagonist, preferably~~ telmisartan~~,~~ and the sugar alcohol at a temperature of ≥ 50°C;

e) cooling the solution to ambient temperature; and

f) topping up the aqueous solution with purified water to give the desired concentration of the ~~angiotensin-II-receptor antagonist, preferably~~ telmisartan.

~~16~~15. Method according to claim ~~15~~14, wherein steps b) to d) are carried out at a temperature between 70°C and 80°C.

~~17~~16. Method according to one of claims ~~15~~ 14 or ~~16~~15, wherein the process comprises the following additional step:

g) adding one or more synthetic sugar substitutes, flavorings and/or preservatives with stirring at ambient temperature.

~~18~~17. Method according to claim ~~17~~16, wherein the additional step g) is carried out between steps e) and f).

~~19~~18. Method according to claim ~~14~~13, characterised in that the pharmaceutical solution is designing to treat hypertension or kidney disease in humans or animals.

~~20~~19. Glass or plastics container with or without dosing aid containing the drinkable solution according to any one of claims 1 to ~~13~~12.