[1], comprising 0.1 mg, 0.3 mg, 0.5 mg, 0.8 mg, 2.8 mg or 5.2 mg of pioglitazone; or a salt of pioglitazone corresponding to 0.1 mg, 0.3 mg, 0.5 mg, 0.8 mg, 2.8 mg or 5.2 mg as pioglitazone.

[4] The sustained-release preparation of any of the above-mentioned [1] - [3], wherein the pioglitazone or a salt thereof is pioglitazone hydrochloride.

[5] The sustained-release preparation of any of the above-mentioned [1] - [4], further comprising a gel forming polymer and a gel forming promoter.

[6] The sustained-release preparation of the above-mentioned [5], wherein the gel forming polymer is polyethylene oxide.

[7] The sustained-release preparation of the above-mentioned [6], wherein the polyethylene oxide is

1) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide in the preparation is from (7xM+1500) to (14.5xM+5410), wherein M shows a value calculated by a weight average molecular weight of polyethylene oxide x 1/10000 when one kind of polyethylene oxide is used; or

2) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide having the highest average molecular weight in the preparation is from (14xM-300) to (~~19xM+6700~~17xM+7700), wherein M shows a value calculated by a weight'average molecular weight of polyethylene oxide having the highest average molecular weight among the polyethylene oxides used x 1/10000 when two or more kinds of polyethylene oxides having different average molecular weights are used.

[8] The sustained-release preparation of any of the above-mentioned [5] - [7], wherein the gel forming promoter is a water-soluble hydrophilic base or water-insoluble hydrophilic base.

[9] The sustained-release preparation of the above-mentioned [8], wherein the water-soluble hydrophilic base is one kind or

a combination of two or more kinds selected from lactose, glucose, mannitol and trehalose, and the water-insoluble hydrophilic base is one kind or a combination of two or more kinds selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose.

[10] The sustained-release preparation of any of the above-mentioned [1] - [9], which is a tablet.

[11] The sustained-release preparation of the above-mentioned [10], which has a tablet weight of 60 - 600 mg.

[12]. The sustained-release preparation of any of the above-mentioned [1] - [11], wherein the pioglitazone or a salt thereof has an average particle size of 1 to 25 pm.

[13] A sustained-release preparation comprising pioglitazone or a salt thereof, a gel forming polymer and a gel forming promoter.

[14] The sustained-release preparation of the above-mentioned [13], wherein the gel forming polymer is polyethylene oxide.

[15] The sustained-release preparation of the above-mentioned [14], wherein the polyethylene oxide is

1) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide in the preparation is from (7xM+1500) to (14.5xM+5410), wherein M shows a value calculated by a weight average molecular weight of polyethylene oxide x 1/10000 when one kind of polyethylene oxide is used; or

2) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide having the highest average molecular weight in the preparation is from (14xM-300) to (~~19xM+6700~~17xM+7700), wherein M shows

a value calculated by a weight average molecular weight of polyethylene oxide having the highest average molecular weight among the polyethylene oxides used x 1/10000 when two or more kinds of polyethylene oxides having different average molecular weights are used.

CLAIMS

~~1. A sustained-release preparation comprising pioglitazone or a salt thereof, which shows a dissolution ratio of pioglitazone of average 25-58% at the 2-hour time point, and average 60-100% at the 4-hour time point, in a dissolution test according to the 50 rpm USP Paddle Method and using pH 2.0 KCl/HCl buffer at 37°C as a test solution.~~

~~2. The sustained-release preparation according to claim 1, comprising 0.1 – 8 mg of pioglitazone; or a salt of pioglitazone corresponding to 0.1 – 8 mg as pioglitazone.~~

~~3. The sustained-release preparation according to claim 1, comprising 0.1 mg, 0.3 mg, 0.5 mg, 0.8 mg, 2.8 mg or 5.2 mg of pioglitazone; or a salt of pioglitazone corresponding to 0.1 mg, 0.3 mg, 0.5 mg, 0.8 mg, 2.8 mg or 5.2 mg as pioglitazone.~~

~~4. The sustained-release preparation according to any of claims 1 to 3, wherein the pioglitazone or a salt thereof is pioglitazone hydrochloride.~~

~~5~~1. A sustained-release preparation comprising pioglitazone or a salt thereof, ~~a gel forming polymer~~polyethylene oxide and a gel forming promoter~~,~~.

wherein the gel forming promoter is one kind or a combination of two or more kinds of water-soluble hydrophilic base selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic base selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose.

~~6. The sustained-release preparation according to claim 5, wherein the gel forming polymer is polyethylene oxide.--~~

~~7~~2. The sustained-release preparation according to claim ~~6~~1, wherein the polyethylene oxide is

1) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide in the preparation is from (7×M+1500) to

(14.5×M+5410), wherein M shows a value calculated by a weight average molecular weight of polyethylene oxide x 1/10000 when one kind of polyethylene oxide is used; or

2) contained such that the product of the weight average molecular weight x 1/10000 and the content (%) of polyethylene oxide having the highest average molecular weight in the preparation is from (14×M-300) to (~~19×M+6700~~17×M+7700), wherein M shows a value calculated by a weight average molecular weight of polyethylene oxide having the highest average molecular weight among the polyethylene oxides used x 1/10000 when two or more kinds of polyethylene oxides having different average molecular weights are used.

~~8~~3. The sustained-release preparation according to claim ~~6~~1, wherein the polyethylene oxide has a weight average molecular weight of not less than 1,000,000 and less than 4,000,000, and is contained at a ratio of 50 - 80 wt% of the preparation.

~~9~~4. The sustained-release preparation according to claim ~~6~~1, wherein the polyethylene oxide has a weight average molecular weight of not less than 4,000,000 and not more than 10,000,000, and is contained at a ratio of 5 - 70 wt% of the preparation.

~~10. The sustained-release preparation according to any of claims 5 to 9, wherein the gel forming promoter is a water-soluble hydrophilic base or water-insoluble hydrophilic base.~~

~~11. The sustained-release preparation according to claim 10, wherein the water-soluble hydrophilic base is one kind or a combination of two or more kinds selected from lactose, glucose, mannitol and trehalose, and the water-insoluble hydrophilic base is one kind or a combination of two or more kinds selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and~~

~~carmellose.~~

5. The sustained-release preparation according to claim 1 or 2, which shows a dissolution ratio of pioglitazone of average 25-58% at the 2-hour time point, and average 60-100% at the 4-hour time point, in a dissolution test according to the 50 rpm USP Paddle Method and using pH 2.0 KCl/HCl buffer at 37°C as a test solution.

6. The sustained-release preparation according to any of claims 1 to 5, comprising 0.1 - 8 mg of pioglitazone; or a salt of pioglitazone corresponding to 0.1 - 8 mg as pioglitazone.

7. The sustained-release preparation according to claim 6, comprising 0.1 mg, 0.3 mg, 0.5 mg, 0.8 mg, 2.8 mg or 5.2 mg of pioglitazone; or a salt of pioglitazone corresponding to 0.1 mg, 0.3 mg, 0.5 mg, 0.8 mg, 2.8 mg or 5.2 mg as pioglitazone.

8. The sustained-release preparation according to any of claims 1 to 7, wherein the pioglitazone or a salt thereof is pioglitazone hydrochloride.

~~12~~9. The sustained-release preparation according to any of claims ~~5~~1 to ~~11~~8, which is a tablet.

~~13~~10. The sustained-release preparation according to claim ~~12~~9, which has a tablet weight of 60 - 600 mg.

~~14. The sustained-release preparation according to any of claims 5 to 13, wherein the pioglitazone or a salt thereof is pioglitazone hydrochloride.~~

~~15~~11. The sustained-release preparation according to any of claims ~~5~~1 to ~~14~~10, wherein the pioglitazone or a salt thereof has an average particle size of 1 to 25 μm.

~~16~~12. A method of producing a sustained-release preparation, comprising

a step of granulating a mixture containing pioglitazone or a salt thereof, a gel forming promoter and polyethylene oxide while spraying an aqueous solution or dispersion containing a gel forming promoter, and compression-molding the obtained granules;

a step of granulating a mixture containing a gel forming promoter and polyethylene oxide while spraying an aqueous solution or dispersion containing a gel forming promoter, mixing the obtained granules with pioglitazone or a salt thereof, and compression-molding the obtained mixture; or

a step of compression-molding a mixture containing pioglitazone or a salt thereof, a gel forming promoter and polyethylene oxide, ~~.~~ wherein the gel forming promoter is one kind or a combination of two or more kinds of water-soluble hydrophilic base selected from lactose, glucose, mannitol and trehalose; or one kind or a combination of two or more kinds of water-insoluble hydrophilic base selected from starch, partially pregelatinized starch, crospovidone, crystalline cellulose, carmellose calcium and carmellose.

~~17. The sustained-release preparation according to any of claims 1 to 15, which is used for the prophylaxis and/or delayed onset or suppression of progression of Alzheimer's~~

~~disease.~~ 13. Use of pioglitazone or a salt thereof for the production of the sustained-release preparation according to any of claims 1 to 11 which is for the prophylaxis and/or delayed onset or suppression of progression of Alzheimer's disease.

~~18. A method of preventing and/or delaying onset or suppressing progression of Alzheimer's disease, comprising administering the sustained-release preparation according to any of claims 1 to 15 to a subject in need of the administration thereof.~~