CLAIMS

1. A pharmaceutical tablet comprising as active ingredients,

i) between 1.5 and 20% of vildagliptin, or a pharmaceutically acceptable salt thereof basis on weight of the active ingredients,

ii) between 80 and 98.5% of metformin or a pharmaceutically acceptable salt thereof basis on weight of the active ingredients,

and wherein metformin is in the form of granules produced by melt granulation wherein said granules comprise;

i) between 1 and 20% or between 3 and 13%, by weight on a dry weight basis of a pharmaceutically acceptable binder,

ii) between 4.9 and 12% or between 7.5 and 10.5% by weight on a dry weight basis of a pharmaceutically acceptable binder, or

iii) between 7.5 and 17.5% or between 12.5 and 17.5% by weight on a dry weight basis of a pharmaceutically acceptable binder;

and wherein the tablet has feature (A) or (B):

(A) the tablet comprises between 80 and 96% by weight on a dry weight basis of active ingredients, wherein the active ingredients consist of vildagliptin and metformin, or in each case a pharmaceutically acceptable salt thereof;

(B) the tablet comprises between 50 and 98% by weight on a dry weight basis of active ingredients, wherein the active ingredients consist of vildagliptin and metformin, or in each case a pharmaceutically acceptable salt thereof, and the tablet has a dispersion time of less than 15 minutes according to the British Pharmacopoeia test 1988.

2. A tablet according to claim 1, wherein the binder is selected from starches; celluloses and derivatives thereof; sucrose; dextrose; corn syrup; polysaccharides; and gelatin.

3. A tablet according to claim 1 to 2, wherein the binder is a cellulose or derivative thereof, selected from microcrystalline cellulose, hydroxypropyl cellulose, hydroxylethyl cellulose and hydroxylpropylmethyl cellulose.

4. A tablet according to any of claims 1 to 3, wherein at least one conventional pharmaceutically acceptable excipient can be added to the composition.

5. A tablet according to claim 4, wherein the pharmaceutically acceptable excipient is selected from binders, diluents, disintegrants, lubricants, solid fillers, glidants and

carriers.

6. A tablet according to any of claims 1 to 5, wherein the composition contain not more than 25% or 20%, 17.5, 15% or 11 % by weight on a dry weight basis of an excipient including a pharmaceutically acceptable binder.

7. A tablet according to any of claims 1 to 6 comprising;
i) between 1 and 12% or between 2.9 and 11% by weight on a dry weight basis of a pharmaceutically acceptable binder and optionally between 0.1 and 10% by weight on a dry weight basis of a further pharmaceutically acceptable excipient, or
ii) between 7 .5 and 17 .5% or between 12.5 and 17 .5% by weight on a dry weight basis of a pharmaceutically acceptable binder and optionally between 0.1 and 10% by weight on a dry weight basis of a further pharmaceutically acceptable excipient.

8. A tablet according to any of claims 1 to 7, wherein the further pharmaceutically acceptable excipient is a lubricant.

9. A tablet according to any of claims 1 to 8, comprising between 0.1 % and 5%, between 0.1 % and 2%, or between 0.5% and 1.5% by weight of the composition of a pharmaceutically acceptable lubricant.

10. A tablet according to claims 8 or 9, wherein the lubricant is magnesium stearate.

11. A tablet according to any of claims 1 to 10, wherein the metformin granules are produced by melt granulation, with the binder.

12. A tablet according to any of claims 1 to 11, wherein vildagliptin or a pharmaceutical salt thereof represent between 1.5 and 20% of the active ingredients.

13. A tablet according to any of claims 1 to 12, wherein vildagliptin is in the form of particles.

14. A tablet according to any of claims 1 to 13, wherein vildagliptin is in the form of particles;
i) wherein at least 40%, 60%, 80% or 90% of vildagliptin has a particle size distribution of less than 250 μm,

ii) wherein at least 40%, 60%, 80% or 90% of vildagliptin has a particle size distribution between 10 and 250 μm, or

iii) wherein at least 25% or at least 35% of the particle size distribution is between 50 and 150 μ m.

15. A tablet according to any of claims 1 to 14, which is in the form of a compressed tablet or directly compressed tablet.

16. A tablet according to any of claims 1 to 15, obtained by direct compression of the metformin granules with vildagliptin and optionally at least one pharmaceutically acceptable excipient.

17. A tablet according to any of claims 1 to 8, which is additionally film coated.

18. A tablet according to any of claims 1 to 17, wherein the formulation represents one of the layers of a bilayer or trilayer tablet.

19. A tablet according to any of claims 1 to 18, comprising;

i) between 25 mg and 100 mg of vildagliptin or a pharmaceutical salt thereof, or

ii) 25 mg, 50 mg or 100 mg of vildagliptin or a pharmaceutical salt thereof.

20. A tablet according to any of claims 1 to 19, comprising;

i) between 50 and 2000 mg or 250 to 1000 mg of metformin or a pharmaceutical salt thereof, or

ii) 250 mg, 500 mg, 850 mg or 1000 mg of metformin or a pharmaceutical salt thereof.

21. A tablet according to any of claims 1 to 20, comprising

i) 25 mg of vildagliptin and 250 mg of metformin, or in any case a pharmaceutical salt thereof,

ii) 25 mg of vildagliptin and 500 mg of metformin, or in any case a pharmaceutical salt thereof,

iii) 25 mg of vildagliptin and 850 mg of metformin, or in any case a pharmaceutical salt thereof,

iv) 25 mg of vildagliptin and 1000 mg of metformin, or in any case a pharmaceutical salt thereof,

v) 50 mg of vildagliptin and 500 mg of metformin, or in any case a pharmaceutical salt

thereof,

vi) 50 mg of vildagliptin and 850 mg of metformin, or in any case a pharmaceutical salt thereof, or

vii) 50 mg of vildagliptin and 1000 mg of metformin, or in any case a pharmaceutical salt thereof.

22. A process for preparing a pharmaceutical composition comprising a DPP-IV inhibitor which is vildagliptin or a pharmaceutical salt thereof and metformin or in any case a pharmaceutical salts thereof, which comprises:;

i) granulating metformin and a binder,

ii) drying granules containing metformin and the binder,

iii) blending the DPP-IV inhibitor, drug substance which is vildagliptin or a pharmaceutical salt thereof with the granules containing metformin and the binder,

iv) blending a lubricant with the mixture obtained on step iii),

wherein the granulation of step i) is a melt granulation and the binder is a cellulose or derivative thereof, selected from microcrystalline cellulose, hydroxypropyl cellulose, hydroxylethyl cellulose and hydroxylpropylmethyl cellulose.

23. A process for preparing a pharmaceutical tablet comprising between 80 and 96% by weight on a dry weight basis of active ingredients, wherein the active ingredients consist of a DPP-IV inhibitor which is vildagliptin or a pharmaceutical salt thereof and metformin or in any case a pharmaceutical salts thereof, which comprises;

i) granulating metformin and a binder,

ii) drying granules containing metformin and the binder,

iii) blending the DPP-IV inhibitor, drug substance which is vildagliptin or a pharmaceutical salt thereof with the granules containing metformin and the binder,

iv) blending a lubricant with the mixture obtained on step iii),

v) compressing the resulting blend to form tablets in unit dosage form,

wherein the granulation of step i) is a melt granulation.

24. A process according to any of claims 22 or 23, wherein during step ii) the granules are dried to an LOD of 0.5-3.5%, or an LOD of 1.5 - 2.4%.

25. A process according to any of claims 22 to 24, wherein at the end of step ii) metformin or a pharmaceutical salt thereof, is in the form of granules comprising between 1 and 25% or between 3 and 13% or between 4.9 and 12% or between 7.5 and

10.5%, or between 7.5 and 17.5% or between 12.5 and 17,5% by weight on a dry weight basis of a pharmaceutically acceptable binder.

26. A process according to any of claims 22 to 25, wherein at least one further pharmaceutically acceptable excipitent is added to the mixture to be blended during step i) or during step iii).

27. A process according to claim 26, wherein the further pharmaceutically acceptable excipitent is a diluent or a desintegrant.

28. A process according to any of claims 23 to 27, wherein a further coating step is applied to tablet resulting from step v).

29. A process according to any of claims 22 to 28, comprising a granulation step i) wherein metformin and the binder are blended and the blend is passed through an extruder for melt granulation.

30. A process according to claim 29, wherein the extruder is set at between 140 and 220 °C, or between 155 and 205°C or between 170 and 190 °C at mixing zone.

31. A process according to any of claims 23 to 30, wherein the binder is a cellulose or derivative thereof, selected from microcrystalline cellulose, hydroxypropyl cellulose, hydroxylethyl cellulose and hydroxylpropylmethyl cellulose.

32. A tablet according to any of claims 1 to 21, wherein Metformin is in the form of Metformin HCl.

33. A process according to anyone of claims 22 to 31, wherein Metformin is in the form of Metformin HCl.

34. A tablet according to any of claims 1 to 21 or claim 32 wherein;
- the tablet hardness is comprised between 60 and 340 N,
- the tablet friability is lower than 0.8%, and
- the tablet thickness is comprised between 4.5 and 8.3 mm.

35. A process according to any one of claims 22 to 31, or 33 wherein;

- the tablet hardness is comprised between 60 and 340 N,
- the tablet friability is lower than 0.8%, and
- the tablet thickness is comprised between 4.5 and 8.3 mm.

36. A tablet according to claim 34, wherein;
- the tablet hardness is comprised between 60 and 340 N,
- the tablet friability is lower than 0.8%,
- the tablet thickness is comprised between 4.5 and 8.3 mm,
- at least 70% of vildagliptin is dissolved within 30 minutes by using the Paddle method, and
- at least 80% of metformin HCl is dissolved within 45 minutes by using the Paddle method.

37. A process according to claim 35, wherein;
- the tablet hardness is comprised between 60 and 340 N,
- the tablet friability is lower than 0.8%,
- the tablet thickness is comprised between 4.5 and 8.3 mm,
- at least 70% of vildagliptin is dissolved within 30 minutes by using the Paddle method, and
- at least 80% of metformin HCl is dissolved within 45 minutes by using the Paddle method.