CLAIMS

1. A pharmaceutical tablet comprising as active ingredients,

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

ii) between 80 to 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 to 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 to 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 to 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 any of claims 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 does not contain more than 25% or 20%, 17.5, 15% or 11 % by weight on a dry weight basis of a pharmaceutically acceptable excipient including the 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 % to 5%, between 0.1 % to 2%, or between 0.5% to 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 composition or tablet according to any of claims 1 to 11, wherein vildagliptin or a pharmaceutical salt thereof represent between 1.5 to 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 to 250 μm, or

iii) wherein at least 25% or at least 35% of the particle size distribution is between 50 to 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 to 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 tablet according to any of claims 1 to 21, wherein Metformin is in the form of Metformin HCI.

23. A tablet according to any of claims 1 to 21 or claim 22 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.

24. A tablet according to claim 23, 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 HCI is dissolved within 45 minutes by using the Paddle method.