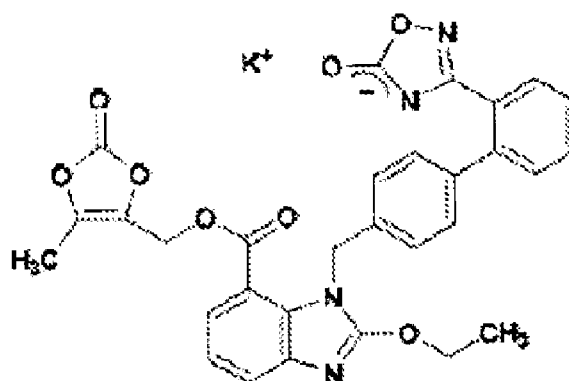




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- Declarations under Rule 4.17:**
- as to the identity of the inventor (Rule 4.17(i))
 - as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
 - as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

[Continued on next page]

(54) **Title:** NOVEL POLYMORPHS OF AZILSARTAN MEDOXOMIL POTASSIUM

Formula I

(57) **Abstract:** Novel forms of Azilsartan medoxomil potassium (Formula I), their preparation and pharmaceutical compositions are provided. New polymorphic forms of Azilsartan medoxomil potassium, their preparation and pharmaceutical compositions are also provided.



— *of inventorship (Rule 4.17(iv))*

— *with amended claims (Art. 19(1))*

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AMENDED CLAIMS

received by the International Bureau on 02 September 2013 (02.09.2013)

1. Polymorphic form I of Azilsartan medoxomil potassium.
2. The polymorphic form I of Azilsartan medoxomil potassium according to claim 1 is characterized by X-ray powder diffraction pattern having peaks at about 6.081, 7.237, 9.237, 10.036, 11.273, 11.625, 11.958, 13.333, 16.047, 20.306, 22.340, 22.634, 23.368, and 24.172, ± 0.2 degrees two-theta.
3. The polymorph form I of Azilsartan medoxomil potassium according to claim 1, wherein the polymorph has a DSC extrapolated melting temperature on set of 152.67°C.
4. The polymorph form I of Azilsartan medoxomil potassium according to claim 1, wherein the polymorph has a DSC peak melting temperature of about 166.93°C.
5. Polymorphic form II of Azilsartan medoxomil potassium sesquihydrate.
6. The polymorphic form II of Azilsartan medoxomil potassium sesquihydrate according to claim 5 is characterized by X-ray diffraction pattern with peak at about 9.230, 10.040, 11.576, 13.280, 16.088, 20.476, 21.132, 23.493, and 24.217 ± 0.2 degrees two-theta.
7. The polymorphic form II of Azilsartan medoxomil potassium sesquihydrate according to claim 5, wherein the polymorph has a DSC extrapolated melting temperature on set of 136.62°C.
8. The polymorphic form II of Azilsartan medoxomil potassium sesquihydrate according to claim 5, wherein the polymorph has a DSC peak melting temperature of about 150.78°C.
9. The polymorphic form II of Azilsartan medoxomil potassium sesquihydrate according to claim 5, wherein the polymorph has a thermogravimetry confirmed that

the presence of sesquihydrate by exhibiting a weight loss of 4.48 % which is corresponds to mole ratio of water to drug of 1.5%.

10. Polymorphic form III of Azilsartan medoxomil potassium hemihydrate.
11. The polymorphic form III of Azilsartan medoxomil potassium hemihydrate according to claim 10 is characterized by X-ray diffraction pattern with peaks at about 6.885, 7.033, 12.353, 16.035, 16.515, 17.039, 22.552, 23.117, and 24.936 ± 0.2 degrees two-theta.
12. The polymorphic form III of Azilsartan medoxomil potassium hemihydrate according to claim 10, wherein the polymorph has a DSC extrapolated melting temperature on set of 88.42 & 112.60°C.
13. The polymorphic form III of Azilsartan medoxomil potassium hemihydrate according to claim 10, wherein the polymorph has a DSC peak melting temperature of about 98.63 & 124.14°C.
14. The polymorphic form III of Azilsartan medoxomil potassium hemihydrate according to claim 10, wherein the polymorph has a thermogravimetry confirmed that the presence of hemihydrate by exhibiting a weight loss of 1.6 % which is corresponds to mole ratio of water to drug of 0.5%.
15. Polymorphic form IV of Azilsartan medoxomil potassium monohydrate.
16. The polymorphic form IV of Azilsartan medoxomil potassium monohydrate according to claim 15 is characterized by X-ray diffraction pattern with peak at about 7.080, 7.981, 12.881, 13.391, 15.960, 16.329, 16.801, 17.160, 23.019, 24.790, 26.006, and 26.546 ± 0.2 degrees two-theta.

17. The polymorphic form IV of Azilsartan medoxomil potassium monohydrate according to claim 15, wherein the polymorph has a DSC extrapolated melting temperature on set of 103.78°C.
18. The polymorphic form IV of Azilsartan medoxomil potassium monohydrate according to claim 15, wherein the polymorph has a DSC peak melting temperature of about 110.92°C.
19. The polymorphic form IV of Azilsartan medoxomil potassium monohydrate according to claim 15, wherein the polymorph has a thermogravimetry confirmed that the presence of monohydrate by exhibiting a weight loss of 2.65 % which is corresponds to mole ratio of water to drug of 1.0%.
20. Polymorphic form V of Azilsartan medoxomil potassium.
21. The polymorphic form V of Azilsartan medoxomil potassium according to claim 20 is characterized by X-ray diffraction pattern with peak at about 7.108 ± 0.2 degrees two-theta.
22. The polymorphic form V of Azilsartan medoxomil potassium which is further characterized by X-ray diffraction pattern showing the presence of semi crystalline nature.
23. The polymorphic form V of Azilsartan medoxomil potassium according to claim 20, wherein the polymorph has a DSC extrapolated melting temperature on set of 84.68 °C.
24. The polymorphic form V of Azilsartan medoxomil potassium claim 20, wherein the polymorph has a DSC peak melting temperature of about 104.63 °C.
25. Amorphous Form of Azilsartan medoxomil potassium.

26. Amorphous form of Azilsartan medoxomil potassium according to claim 25 is designated as Form VI which is further characterized by X-ray diffraction pattern.
27. A process for the preparation of amorphous Form VI of Azilsartan medoxomil potassium comprising:
- a) dissolving Azilsartan medoxomil potassium in organic solvent;
 - b) heating the solution;
 - c) evaporating off the organic solvent partially or completely;
 - d) isolating the amorphous Form VI Azilsartan medoxomil potassium;
 - e) drying the amorphous Form VI Azilsartan medoxomil potassium.
28. The process according to claim 27, wherein the said organic solvent is C₁-C₈ alcohol or mixture thereof.
29. The process according to claim 28, wherein the preferred organic solvent is methanol.