SUSTAINED RELEASE FORMULATION OF ALPRAZOLAM

Abstract: The present invention is directed towards the preparation of extended release Alprazolam formulation. The formulation thus obtained provides an efficient mode of delivery of Alprazolam in a continuous manner.
For two-letter codes and other abbreviations, refer to the “Guidance Notes on Codes and Abbreviations” appearing at the beginning of each regular issue of the PCT Gazette.
WE CLAIM:

1. A sustained release tablet composition comprising:
   (a) a therapeutically effective amount of alprazolam,
   (b) combination of hydroxy-propyl-methyl cellulose of varying viscosity, wherein first one has viscosity in the range of 1500 cp to 2,25,000 cp and second one has viscosity in the range of 2 cp to 400 cp, wherein the amount of hydroxyl-propyl-methyl cellulose is in the range of 70 to 100 mg in the ratio of 65:35 to 85:15, and
   (c) pharmaceutically acceptable excipients.

2. A composition as claimed in claim 1, wherein the amount of alprazolam is between 1mg and 5mg.

3. A composition as claimed in claim 1, wherein the alprazolam is a pharmaceutically acceptable salt of alprazolam.

4. A composition as claimed in claim 1, wherein the high viscosity HPMC has about 19% to about 24% by weight of methoxy substituent, and about 4% to about 12% by weight of hydroxypropoxy substituent.

5. A composition as claimed in claim 1, wherein the first HPMC is selected from the group comprising of HPMC having viscosity in the range of-
   (a) 3000 cp to 5600 cp;
   (b) 11250 cp to 21000 cp and
   (c) 80000 cp to 120000 cp.

6. A composition as claimed in claim 1, wherein the first HPMC preferably used is having the viscosity in range of 3000 cp to 5600 cp.

7. A composition as claimed in claim 1, wherein the HPMC is selected from the group comprising of HPMC having viscosity in the range of 2 cp to 5 cp or 80 cp to 120 cp.
8. A composition as claimed in claim 1, wherein the HPMC is selected having viscosity in the range of 80 cp to 120 cp.

9. A composition as claimed in claim 1, wherein the preferable ratio of first HPMC to second HPMC is 65:35 to 75:25.

10. A composition as claimed in claim 1, wherein the more preferable ratio of first HPMC to second HPMC is 70:30.

11. A composition as claimed in claim 1, wherein the composition provides a total daily dose of about 0.5 mg to about 3 mg of alprazolam.

12. A composition as claimed in claim 1, wherein the composition is configured to release alprazolam at a rate that ranges between 20% to 40% in 4 hours to more than 70% in 14 hours of the total dose of alprazolam after the exposure to phosphate buffer having pH 6.0 ± 0.1.

13. A composition as claimed in claim 1, wherein the $C_{\max}$ occurs more than 3 hours after administration.

14. The process for the preparation of sustained release tablet composition of Alprazolam, comprising the steps of:
mixing Alprazolam with lactose and optionally the coloring agents,
sifting the mixture to obtain the homogeneous blend,
adding HPMC having the viscosity in the range of 3000 cp to 5600 cp and HPMC having viscosity in the range of 80 cp to 120 cp the blend, granulating the blend with water to form wet mass,
drying the wet mass, forming granules and compressing to form tablet.