Claims

1. A stable, non-aqueous oromucosal solution of Zolpidem or its pharmaceutically acceptable salts comprising:

   0.5 to 10 % w/v of Zolpidem or pharmaceutically acceptable salts thereof,

   up to 30% v/v a penetration enhancer, is selected from a group comprising lower chain alcohol with a carbon chain length of 1 to 5, sodium glycocholate, sodium deoxycholate, sodium taurocholate, sodium glycodeoxycholate, sodium taurodeoxycholate, oleic acid, capric acid, lauric acid, lecithin, myristic acid, palmitic acid, lysophosphatidylcholine, phosphatidylcholine, azone, cyclodextrin, sodium lauryl sulphate, Polyoxyethylene-9-laurylether, Polyoxythylene-20-cetylether, Benzalkonium chloride, cetylpyridinium chloride, Vitamin E TPGS, Caprylocaproyl polyoxylglycerides, Stearoyl Macrogolglycerides, Propylene Glycol Dicaprylocaprate or mixtures thereof, and

   at least 40% v/v of a non-aqueous solvent system, is selected from glycerol, propylene glycol, polyethylene glycol, propylene carbonate, glycofurol, isopropyl myristate, isopropyl palmitate, dimethyl sulfoxide, triethyl citrate, dimethyl acetamide, benzyl alcohol, N-methyl-pyrrolidone, dimethyl isosorbide, ethyl acetate or mixture thereof.

   wherein the pH of the formulation is 5 to 9.

2. The stable, non-aqueous oromucosal solution as claimed in claim 1, wherein the solution comprises 2.5% to 10 % w/v of Zolpidem or pharmaceutically acceptable salts thereof.

3. The stable, non-aqueous oromucosal solution as claimed in claims 1-2, wherein the pH of the formulation is in the range of 6 to 9, preferably in the range of 7 to 9.

4. The stable, non-aqueous oromucosal solution as claimed in claim 1, wherein the lower chain alcohol is ethanol or isopropyl alcohol or mixtures thereof.

5. The stable, non-aqueous oromucosal solution as claimed in claims 1-4, wherein the penetration enhancer is in the range of 2 to 30% v/v of the formulation, preferably in the range of 10 to 30% v/v of the formulation.

6. The stable, non-aqueous oromucosal solution as claimed in claims 1-4, wherein the penetration enhancer is in the range of 2 to 25% v/v of the formulation.

7. The stable, non-aqueous oromucosal solution as claimed in claims 1-9, wherein the solution further comprises upto 5% w/v of a polymer selected from poly vinypyrolidone, poly(vinyl pyrrolidone-co-vinyl acetate), polyvinylpolypyrrolidone, polymethacrylates, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose acetate succinate, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl betadex, polyvinyl alcohol, polyacrylic acid or mixtures thereof.