CLAIMS

1. A stable topical pharmaceutical gel composition of ~~an~~ amlodipine ~~salt~~ besylate comprising:

about 0.01-1 % w/w of ~~an~~ amlodipine ~~salt~~ besylate, as measured as the free base, wherein said amlodipine besylate is present in a dissolved state in said gel, and wherein the degradation impurities of said amlodipine besylate is less than about 2.5% for a storage period of at least 24 months at a temperature of about 2-8° C.;

about 5-75 % w/w of at least one glycol solvent;

about 0.1-10 % w/w of ~~at least one gelling agent~~ hydroxyethyl cellulose;

~~about 0.001-5 % w/w of at least one preservative;~~

about ~~5~~30-~~75~~50 % w/w of glycerin;

about ~~1~~5-~~20~~15 % w/w of ethanol; and

about ~~10~~15-~~40~~35 % w/w of water.

~~2. The topical pharmaceutical gel composition of claim 1, wherein the amlodipine salt is chosen from amlodipine besylate, amlodipine maleate, amlodipine mesylate, amlodipine adipate, amlodipine camsylate and amlodipine nicotinate.~~

~~3. The topical pharmaceutical gel composition of claim 1, wherein the amlodipine salt is amlodipine besylate.~~

~~4.~~2. The stable topical pharmaceutical gel composition ~~of any one of claims 1 to 3~~ according to claim 1, wherein ~~the~~ said at least one glycol solvent is chosen from propylene glycol, polyethylene glycol, ethylene glycol, butylene glycol, hex~~al~~ylene glycol, and mixtures thereof.

~~5.~~3. The stable topical pharmaceutical gel composition ~~of claim 4~~ according to claim 2, wherein ~~the~~ said glycol solvent is propylene glycol.

4. The stable topical pharmaceutical gel composition according to claim 1, wherein said amlodipine besylate is present at a concentration of 0.01-1% w/w as measured as the free base, wherein said at least one glycol solvent is propylene glycol and is present at a concentration of 5-75% w/w, wherein said hydroxyethyl cellulose is present at a

concentration of 0.1-10% w/w, wherein said glycerin is present at a concentration of 30-50% w/w, wherein said ethanol is present at a concentration of 5-15% w/w, wherein said water is present at a concentration of 15-35% w/w, wherein said stable topical pharmaceutical gel composition further comprises methyl parahydroxybenzoate, and wherein said methyl parahydroxybenzoate is present at a concentration of 0.01-5% w/w.

5. The stable topical pharmaceutical gel composition according to claim 1, wherein said amlodipine besylate is present at a concentration of about 0.1-1% w/w, as measured as the free base.

6. The stable topical pharmaceutical gel composition according to claim 4, wherein the degradation impurities of said amlodipine besylate is less than 2.5% for a storage period of at least 24 months at a temperature of about 2-8° C.

~~6. The topical pharmaceutical gel composition of any one of claims 1 to 5, wherein the at least one gelling agent is chosen from carbomers, xanthan gum, acacia, tragacanth, sodium alginate, gelatin, modified starches, hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxypropyl methylcellulose, carboxymethyl cellulose, carboxymethyl cellulose sodium, hydroxypropyl methylcellulose phthalate, methyl cellulose, co-polymers formed between maleic anhydride and methyl vinyl ether, methacrylate derivatives, polyethylene oxides, polyoxyethylene-polyoxypropylene copolymers, polyvinyl alcohol and mixtures thereof.~~

~~7. The topical pharmaceutical gel composition of claim 6, wherein the gelling agent is hydroxyethyl cellulose.~~

~~8. The topical pharmaceutical gel composition of any one of claims 1 to 7, wherein the at least one preservative is chosen from methyl paraben, propyl paraben, methyl parahydroxybenzoate, chlorocresol, thomersal, sorbic acid, potassium sorbate and mixtures thereof.~~

~~9. The topical pharmaceutical gel composition of claim 8, wherein the preservative is methyl parahydroxybenzoate.~~

10. The topical pharmaceutical gel composition of any one of claims 1 to 9, wherein said topical pharmaceutical gel composition further comprises at least one antioxidant.

11. The topical pharmaceutical gel composition of claim 10, wherein said at least one antioxidant is present in an amount equal to or less than 5% w/w.

12. The topical pharmaceutical gel composition of claim 10 or 11, wherein the antioxidant is selected from the group consisting of edetate disodium, sodium sulphite, sodium metabisulfite, propyl gallate, edetate trisodium, tocopherol derivatives, butylated hydroxyl toluene, butylated hydroxyl anisole, ascorbic acid, fumaric acid, malic acid, citric acid, and mixtures thereof.

13. A topical pharmaceutical gel composition of amlodipine besylate comprising:

about 0.01-1 % w/w of amlodipine besylate, as measured as the free base;
about 5-75 % w/w of at least one glycol solvent;
about 0.1-10 % w/w of hydroxyethyl cellulose;
about 5-75 %w/w of glycerin;
about 1-20 % w/w of ethanol; and
about 10-40 % w/w of water.

14. A topical pharmaceutical gel composition of amlodipine besylate comprising:

about 0.01-1 % w/w of amlodipine besylate, as measured as the free base;
about 5-75 % w/w of propylene glycol;
about 0.1-10 % w/w of at least one gelling agent;
about 5-75 %w/w of glycerin;
about 1-20 % w/w of ethanol; and
about 10-40 % w/w of water.

15. A topical pharmaceutical gel composition of amlodipine besylate comprising:

about 0.01-1 % w/w of amlodipine besylate, as measured as the free base;
about 5-75 % w/w of propylene glycol;
about 0.1-10 % w/w of hydroxyethyl cellulose;
about 0.01-5 % w/w of methyl parahydroxybenzoate;
about 5-75 %w/w of glycerin;

about 1-20 % w/w of ethanol; and

about 10-40 % w/w of water.

16. A method for the treatment of an anorectal disease comprising topically applying a topical pharmaceutical gel composition of any one of claims 1 to 15 to a skin surface of a patient in need thereof.

17. The method of claim 16, wherein the active ingredient consists essentially of amlodipine besylate and the amlodipine besylate is present at a concentration of about 0.01% w/w to about 1% w/w, as measured as the free base.

18. The method of claim 16, wherein the active ingredient consists essentially of amlodipine besylate or its salts mixed with local anesthetic such as lidocaine or anti-inflammatory agent such as COX COX-1 or COX-2 inhibitors or their mixtures and the amlodipine besylate is present at a concentration of about 0.01% w/w to about 1% w/w, as measured as the free base.

19. The method of claim 16, wherein said anorectal disease is chosen from hemorrhoids, anal fissure (acute and chronic), painful conditions after anorectal surgery, perianal abscess, prolapsed thrombosed piles, perianal haematoma, cancer invading the sphincters (anorectal cancer), anal herpes, anal warts, anal itching, proctalgia fugax, constipation, anal bleeding and Crohn's disease or another inflammatory bowel disease related anorectal disorders.