What is Claimed:

1. An alcohol-resistant pharmaceutical composition comprising:

(i) an active agent;

(ii) an enteric system;

(iii) an alcohol protectant in an amount sufficient to prevent release of the active agent in the presence of alcohol.

2. The composition of claim 1, wherein the alcohol protectant is selected from the group consisting of an organic-based cellulose acetate phthalate, hypromellose phthalate, Eudragit S, and a mixture of Eudragit L 30 D-55 and Eudragit L 100-55.

3. The composition of claim 1, wherein the amount of alcohol protectant sufficient to prevent release of the active agent in the presence of alcohol is in an amount selected from the group consisting of 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95%, 100%, 150%, 200%, 250%, 300%, 350%, 400%, 450% and 500% by weight gain.

4. The composition of claim 1, wherein the release of the active agent in the presence of alcohol is defined by a percentage of active agent released, which percentage is selected from the group consisting of less than or about 1%, 2%, 5%, 8%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95%, or 99% in 40% ethanolic HCl in 2 hours.

5. The composition of claim 1, wherein after placement in the 0.1N HCl for 2 hours, the composition is placed in phosphate buffer (pH 6.8) for 4 hours, and an amount selected from the group consisting of more than or about 1%, 2%, 5%, 8%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%,

85%, 90%, 95%, and 99% of the active agent is released from the composition.

6. The composition of claim 5, wherein prior to placement in phosphate buffer (pH 6.8 for 4 hours, the composition has been exposed to 40% ethanolic HCl for 2 hours, and less than or about 1%, 2%, 5%, 8%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95%, or 99% of the active agent is released.

7. The composition of claim 5, wherein the percentage of active agent released is less than or about 35% in 40% ethanolic HCl in 2 hrs.

8. The composition of claim 1, wherein the active agent is selected from the group consisting of duloxetine HCl, esomeprazole, rabeprazole sodium, mesalamine, budesonide, lamotrigine, dexlansoprazole, pancreatin, pancrelipase, divalproex sodium, omeprazole, lanzoprazole, diclofenac sodium, valproic acid, fenofibric acid, didanosine, aspirin, bisacodyl, naproxen, erythromycin, sodium rabeprazole, adenovirus vaccine type 4, calcitonin, darapladib, mesalzine, alendronic acid, eprotirome, NE-F (Nephritic factor), glatiramer, CH-1504, bisphosphonate (zoledronic acid) compound, mercaptamine, larazotide, oral insulin, and mixtures or combinations thereof.

9. The composition of claim 1, wherein the enteric system is incorporated into the composition in a form selected from the group consisting of a coating, a layer, a matrix, and combinations thereof.

10. The composition of claim 1, wherein the enteric system comprises components selected from the group consisting of aqueous and organic based hydroxyl propyl methyl cellulose acetate succinate, poly vinyl acetate phthalate, organic based cellulose acetate phthalate, and poly(methacylic acid-co-ethyl acrylate) anionic copolymers.

11. The composition of claim 1, further comprising a disintegrant selected from the group consisting of a swellable material, a superdisintegrant, and mixtures or combinations thereof.

12. The composition of claim 1, further comprising a barrier material disposed between the active agent and the alcohol protectant.

13. An alcohol-resistant pharmaceutical composition comprising and active agent and an alcohol protectant, which alcohol protected formulation releases the active agent in an amount that is less than an amount of active agent released by a commercially equivalent formulation when both the alcohol protected formulation and the commercially equivalent formulation are placed in the same alcohol environment.

14. An alcohol resistant pharmaceutical composition comprising an active agent and an alcohol protectant, which alcohol protected formulation releases less than 5% of the active agent in 40% ethanolic acid (0.1N HCl) in 2 hours, and has a similar dissolution profile in phosphate buffer pH 6.8 in 4 hours when compared to a commercially equivalent formulation.

15. An alcohol resistant pharmaceutical composition comprising an active agent and an alcohol protectant, which alcohol protected formulation has a similar in vitro dissolution profile in 0.1N HCl in 2 hours followed by phosphate buffer pH 6.8 in 4 hours when compared to a commercially equivalent formulation.

16. The composition of claim 12, wherein less than 5% of the active agent is released in 40% ethanolic acid (0.1N HCl) in 2 hours, and wherein the in vitro dissolution profile of the composition in 0.1N HCl in 2 hours followed by phosphate buffer pH 6.8 in 4 hours has an f2 value ≥50 compared to a commercially equivalent formulation.

What is Claimed:

1. An alcohol-resistant pharmaceutical composition comprising:

(i) an active agent;

(ii) an enteric system;

(iii) an alcohol protectant to prevent release of the active agent in the presence of alcohol wherein the alcohol protectant is in an amount of from 10% to 500% by weight gain of each bead.

2. The composition of claim 1, wherein the protectant is selected from the group consisting of an organic-based cellulose acetate phthalate, hypromellose phthalate, ethyl acrylatemethyl methacrylate copolymers, poly (methacylic acid-co-ethyl acrylate) anionic copolymers, and mixtures thereof.

3. The composition of claim 1, wherein the amount of alcohol protectant sufficient to prevent release of the active agent in the presence of alcohol is in an amount selected from the group consisting of 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95% 100%, 150%, 200%, 250%, 300%, 350%, 400%, and 450% by weight gain.

4. The composition of claim 1, wherein the release of the active agent in the presence of alcohol is defined by a percentage of active agent released, which percentage is selected from the group consisting of less than or about 1%, 2%, 5%, 8%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50% in 40% ethanolic HCl in 2 hours.

5. The composition of claim 1, wherein the percentage of active agent released is less than or about 35% in 40% ethanolic HCl in 2 hrs.

6. The composition of claim 1, wherein the active agent selected from the group consisting of duloxetine HCl, esomeprazole, rabeprazole sodium, mesalamine, budesonide, lamotrigine, dexlansoprazole, pancreatin, pancrelipase, divalproex sodium, omeprazole, lanzoprazole, diclofenac sodium, valproic acid, fenofibric acid, didanosine, aspirin, bisacodyl, naproxen, erythromycin, sodium rabeprazole, adenovirus vaccine type 4, calcitonin, darapladib, mesalzine, alendronic acid, eprotirome, NE-F (Nephritic factor), glatiramer, CH-1504, bisphosphonate (zoledronic acid) compound, mercaptamine, larazotide, oral insulin, and mixtures or combinations thereof.

7. The composition of claim 1, wherein the enteric system is incorporated into the composition in a form selected from the group consisting of a coating, a layer, a matrix, and combinations thereof.

8. The composition of claim 1, wherein the enteric system comprises components selected from the group consisting of aqueous and organic based hydroxyl propyl methyl cellulose acetate succinate, poly vinyl acetate phthalate, organic based cellulose acetate phthalate, and poly(methacylic acid-co-ethyl acrylate) anionic copolymers.

9. The composition of claim 1, further comprising a disintegrant selected from the group consisting of a swellable material, a superdisintegrant, and mixtures or combinations thereof.

10. The composition of claim 1, further comprising a barrier material disposed between the active agent and the alcohol protectant.

11. An alcohol-resistant pharmaceutical composition comprising an active agent, an enteric system and an alcohol protectant, wherein the alcohol protectant is in an amount of from 10% to 500% by weight gain of each bead and wherein formulation releases less than 50% of the active agent in 20% ethanolic acid (0.1N HCl) in 2 hours compared to a commercially equivalent formulation when both are placed in the same alcohol environment.

12. An alcohol resistant pharmaceutical composition comprising an active agent, an enteric system containing an enteric component selected from the group consisting of aqueous and organic based hydroxyl propyl methyl cellulose acetate succinate, poly vinyl acetate phthalate, organic based cellulose acetate phthalate, and poly (methacylic acid-co-ethyl acrylate) anionic copolymers and an alcohol protectant, which alcohol protected formulation releases less than 5% of the active agent in 40% ethanolic acid (0.1N HCl) in 2 hours.

13. An alcohol resistant pharmaceutical multiparticulate composition comprising an active agent, an enteric system containing an enteric component selected from the group consisting of aqueous and organic based hydroxyl propyl methyl cellulose acetate succinate, poly vinyl acetate phthalate, organic based cellulose acetate phthalate, and poly (methacylic acid-co-ethyl acrylate) anionic copolymers, and an alcohol protectant selected from the group consisting of an organic-based cellulose acetate phthalate, hypromellose phthalate, ethyl acrylatemethyl methacrylate copolymers, poly (methacylic acid-co-ethyl acrylate) anionic copolymers and mixtures thereof, which alcohol protected formulation has a similar in vitro dissolution profile in phosphate buffer pH 6.8 in 4 hours when compared to a commercially equivalent formulation.

14. The composition of claim 13, wherein less than 5% of the active agent is released in 40% ethanolic acid (0.1N HCl) in 2 hours.

15. An alcohol-resistant pharmaceutical composition comprising:

(i) an active agent, wherein the active agent is duloxetine HCl, fenofibric acid, choline fenofibroate, or esomeprazole;

(ii) an enteric system comprising components selected from the group consisting of aqueous and organic based hydroxyl propyl methyl cellulose acetate succinate, organic based cellulose acetate phthalate, and poly(methacylic acid-co-ethyl acrylate) anionic copolymers,

(iii) an alcohol protectant selected from the group consisting of organic based cellulose acetate phthalate, hydroxypropylmethylcellulose, hypromellose phthalate, ethyl acrylatemethyl methacrylate copolymers, poly (methacylic acid-co-ethyl acrylate) anionic copolymers, and a mixture thereof, and

wherein the alcohol protectant is in an amount of from 20% to 500% by weight gain of each bead and wherein formulation releases less than 50% of the active agent in 20% ethanolic acid (0.1N HCl) in 2 hours.

16. The composition of claims 1, 11, 13 or 15 wherein formulation releases less than 50% of the active agent in 40% ethanolic acid (0.1N HCl) in 2 hours.