SUMMARY ~~OF THE INVENTION~~

[0007] The ~~invention~~present disclosure is related to an alcohol-resistant pharmaceutical composition which pharmaceutical composition includes an active agent having an enteric layer resistant to degradation or dissolution at a pH of less than 5.5 and an alcohol protectant in an amount sufficient to prevent substantial release of the active agent in the presence of alcohol.

[0007a] In an aspect, there is provided an alcohol-resistant pharmaceutical composition comprising:

(i) an active agent;

(ii) an enteric system; and

(iii) an alcohol protectant containing organic based cellulose acetate phthalate to retard 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.

[0007b] In another aspect, there is provided an alcohol-resistant pharmaceutical composition comprising an active agent, an enteric system and an organic based cellulose acetate phthalate 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.

[0007c] In another aspect, there is provided 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 containing an organic based cellulose acetate phthalate.

[0007d] In another aspect, there is provided an alcohol resistant pharmaceutical multiparticulate composition comprising a plurality of beads wherein each bead comprises 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 containing an organic based cellulose acetate phthalate.

[0008] In another ~~aspect~~embodiment, the ~~invention~~present disclosure is related to a composition having an alcohol protectant that prevents release of the active agent from the composition when placed in an alcohol environment in an amount that is less than the amount of active agent released by the same composition without the alcohol protectant in the same alcohol environment.

[0009] Also described is a method of treating a disease with an active agent by administering to a patient afflicted with the disease an effective amount of an alcohol-resistant pharmaceutical composition comprising the active agent suitable for treating the disease.

[0010] In a further ~~aspect~~embodiment, the ~~invention~~present disclosure is related to an alcohol resistant pharmaceutical composition having an active agent and an alcohol protectant, which alcohol protected formulation has a similar in vitro dissolution profile in 40% ethanolic acid (0.1N HCl) for 2 hours (USP I or III) followed by phosphate buffer pH 6.8 (USP I or II) for 4 hours when compared to a commercially equivalent product.

[0011] In yet a further ~~aspect~~embodiment, the ~~invention~~present disclosure is related to an alcohol protected formulation that bioequivalent to a commercially equivalent product.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Fig 1 is a plot of the average released amount of drug, duloxetine hydrochloride(% released) over time (min) in 5%, 20%,