It is desired to provide polymer compositions for use in different applications or end-user products wherein the peroxide contents are not increased even upon storing for long periods of time, thereby providing end-user products with better stability and desired performance.

SUMMARY

[0011] The present disclosure provides a peroxide stable polymer composition comprising: a mixture of (i) 95 *wt.*% to about 99.999 *wt.* % of polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA); and (ii) 0.001 *wt.* % to 5.0 *wt.* % of butylated hydroxy anisole (BHA).

[0011a] In an aspect, there is provided a peroxide stable polymer composition comprising:

a mixture of (i) from 95 *wt.*% to about 99.5 *wt.*% of polyvinylpyrrolidone/vinyl acetate (PVP/VA) copolymer that is a linear random copolymer having PVP monomers in an amount of from 50 *wt.*% to 80 *wt.*%, and VA monomers in an amount of from 20 *wt.*% to 50 *wt.*%; and (ii) from 0.5 *wt.* % to 5.0 *wt.*% of butylated hydroxy anisole (BHA).

[0012] The present disclosure provides a pharmaceutical composition comprising a peroxide stable polymer composition comprising a mixture of 95 *wt.* % to about 99.999 *wt.* % of polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA), and 0.001 *wt.* % to 5 *wt.* % of butylated hydroxy anisole (BHA); and at least one pharmaceutical active ingredient.

[0012a] In another aspect, there is provided a pharmaceutical composition comprising:

(i) a peroxide stable polymer composition comprising a mixture of from 95 *wt.* % to 99.5 *wt.* % of polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA) that is a linear random copolymer having PVP monomers in an amount of from 50 *wt.*% to 80 *wt.*%, and VA monomers in an amount of from 20 *wt.*% to 50 *wt.*%, and from 0.5 *wt.* % to 5 *wt.* % of butylated hydroxy anisole (BHA); and

(ii) at least one active pharmaceutical ingredient (API).

[0013] The present disclosure provides a process for preparing a peroxide stable polymer composition comprising the steps of: (i) preparing a feed mixture comprising 95 *wt.* % to about 99.999 *wt.* % of PVP/VA copolymer and 0.001 *wt.* % to 5 *wt.* % of BHA in an aqueous and/or organic solvent; and (ii) spray drying the feed mixture of process step (i) to form a free-flowing peroxide stable polymer composition comprising a mixture of PVP/VA copolymer and BHA.

[0013a] In another aspect, there is provided a process for preparing a peroxide stable polymer composition comprising the steps of:

(i) preparing a feed mixture comprising from 95 *wt.*% to 99.5 *wt.* % of PVP/VA copolymer that is a linear random copolymer having PVP monomers in an amount of from 50 *wt.*% to 80 *wt.*%, and VA monomers in an amount of from 20 *wt.*% to 50 *wt.*%; and from 0.5 *wt.* % to 5 *wt.* % of BHA in an aqueous and/or organic solvent; and

(ii) spray drying the feed mixture of process step (i) to form a free-flowing peroxide stable polymer composition comprising a mixture of PVP/VA copolymer and BHA.

[0014] The present disclosure provides a peroxide stable polymer composition consisting of: a mixture of (i) 95 *wt.* % to about 99.999 *wt.* % of polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA); and (ii) 0.001 *wt.* % to 5 *wt.* % of butylated hydroxy anisole (BHA).

[0014a] In another aspect, there is provided a peroxide stable polymer composition consisting of:

a mixture of (i) from 95 *wt.* % to 99.5 *wt.* % of polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA) that is a linear random copolymer having PVP monomers in an amount of from 50 *wt.*% to 80 *wt.*%, and VA monomers in an amount of from 20 *wt.*% to 50 *wt.*%; and (ii) 0.5 *wt.* % to 5 *wt.* % of butylated hydroxy anisole (BHA).

What is claimed is:

1. A peroxide stable polymer composition comprising:

a mixture of (i) from 95 *wt.*% to about 99.5 *wt.*% of polyvinylpyrrolidone/vinyl acetate (PVP/VA) copolymer that is a linear random copolymer having PVP monomers in an amount of from 50 *wt.*% to 80 *wt.*%, and VA monomers in an amount of from 20 *wt.*% to 50 *wt.*%; and (ii) from 0.5 *wt.* % to 5.0 *wt.*% of butylated hydroxy anisole (BHA).

2. The peroxide stable polymer composition according to claim 1, wherein the weight ratio of the PVP and VA monomer is 60:40.

3. The peroxide stable polymer composition according to claim 1, wherein the PVP/VA copolymer has a weight average molecular weight ranging from 20,000 to 40,000.

4. The peroxide stable polymer composition according to claim 3, wherein the weight average molecular weight of the PVP/VA copolymer is in the range of from 24,000 to 30,000.

5. The peroxide stable polymer composition according to claim 1, wherein the PVP/VA copolymer has a K value ranging from 10 to 150.

6. The peroxide stable polymer composition according to claim 5, wherein the K value of the PVP/VA copolymer ranges from 25 to 32.

7. The peroxide stable polymer composition according to claim 1, wherein the polymer composition has peroxide content varying in the range of from 0 to 180 *ppm*, based on solid content of the PVP/VA copolymer.

8. The peroxide stable polymer composition according to claim 7, wherein the peroxide content varies in the range of from 0 to 120 *ppm* based on solid content of the PVP/VA copolymer.

9. A pharmaceutical composition comprising:

(i) a peroxide stable polymer composition comprising a mixture of from 95 *wt.* % to 99.5 *wt.* % of polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA) that is a linear random copolymer having PVP monomers in an amount of from 50 *wt.*% to 80 *wt.*%, and VA monomers in an amount of from 20 *wt.*% to 50 *wt.*%, and from 0.5 *wt.* % to 5 *wt.* % of butylated hydroxy anisole (BHA); and

(ii) at least one active pharmaceutical ingredient (API).

10. The pharmaceutical composition according to claim 9, wherein the composition is formulated in a solid dosage form selected from the group consisting of soft gelatin capsule, tablets, capsules, pellets, particulates, granules, powder, disc, caplets or sachets.

11. The pharmaceutical composition according to claim 9, wherein the active ingredient is selected from the group comprising antibiotics, anti-inflammatory agents, antifungal agents, anti-infectives, immunosuppressants, anti-depressants, anti-cancer agents, anti-tubercular agents, cardiovascular agents, gastrointestinal agents, anti-viral agents, anti-psychotic agents, anti-histamines, anti-diabetic agents, cholesterol lowering agents, immune modulators, anti-epileptic agents, analgesic agents, anti-psoriatic agents, anti-pyretics, anti-malarial agents, antiseptics, mucolytics, decongestants, sedatives, anti-coagulants, diuretics, cholinergics, dopaminergics, and mixtures thereof.

12. A process for preparing a peroxide stable polymer composition comprising the steps of:

(i) preparing a feed mixture comprising from 95 *wt.*% to 99.5 *wt.* % of PVP/VA copolymer that is a linear random copolymer having PVP monomers in an amount of from 50 *wt.*% to 80 *wt.*%, and VA monomers in an amount of from 20 *wt.*% to 50 *wt.*%; and from 0.5 *wt.* % to 5 *wt.* % of BHA in an aqueous and/or organic solvent; and

(ii) spray drying the feed mixture of process step (i) to form a free-flowing peroxide stable polymer composition comprising a mixture of PVP/VA copolymer and BHA.

13. The process according to claim 12, wherein the solvent includes at least one solvent selected from the group consisting of isopropanol, ethanol, water, dichloromethane, chloroform, ethyl acetate, ethyl methyl ketone, methanol, acetone, and mixtures thereof.

14. The process according to claim 13, wherein the solvent is selected from the group consisting of water, isopropanol or a mixture thereof.

15. A peroxide stable polymer composition consisting of:

a mixture of (i) from 95 *wt.* % to 99.5 *wt.* % of polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA) that is a linear random copolymer having PVP monomers in an amount of from 50 *wt.*% to 80 *wt.*%, and VA monomers in an amount of from 20 *wt.*% to 50 *wt.*%; and (ii) 0.5 *wt.* % to 5 *wt.* % of butylated hydroxy anisole (BHA).