Claims

1. A liquid oral pharmaceutical composition comprising:
   i.) from about 0.1% to about 20% w/v polyvinylpyrrolidone;
   ii.) from about 5% to about 70% w/v polyethylene glycol;
   iii.) from about 1% to about 30% w/v propylene glycol;
   iv.) from about 1% to 10% w/v guaifenesin; and
   v.) from about 0.01% to about 1.0% w/v phenylephrine.

2. The composition of claim 1, further comprising an anti-tussive.

3. The composition of claim 2, wherein the anti-tussive is dextromethorphan.

4. The composition of claim 1, wherein the composition is a solution or a suspension.

5. The composition of Claim 1, comprising about 0.5% w/v polyvinylpyrrolidone.

6. The composition of Claim 1, comprising about 10% w/v polyethylene glycol.

7. The composition of Claim 1, comprising about 10% w/v propylene glycol.

8. The composition of Claim 1, comprising about 4% w/v guaifenesin.

9. The composition of Claim 1, comprising about 0.10% w/v phenylephrine.

10. The composition of Claim 1, comprising a flavorant.

11. The composition of Claim 1, wherein the composition comprises a ratio of the polyvinylpyrrolidone to the guaifenesin of 1:8 in the presence of the phenylephrine.

12. The composition of Claim 1, wherein the composition is visually free of guaifenesin precipitation for at least 62 days at 4°C.

13. The liquid composition of Claim 1, comprising about 4% w/v guaifenesin and about 0.10% w/v phenylephrine, wherein the composition is visually free of guaifenesin precipitation for 14 days at -20°C.

14. The liquid composition of Claim 1, wherein the composition comprises about 4% w/v guaifenesin and about 0.10% w/v phenylephrine, about less than 2% total phenylephrine degradants, as a percent weight over weight phenylephrine, and about less than 2% loss of phenylephrine from the initial total phenylephrine content, measured over a 3 month time period while stored at 40°C and 75% relative humidity.

15. A liquid oral pharmaceutical composition comprising:

vii.) about 0.2% w/v dextromethorphan;
viii.) about 4% w/v guaifenesin;
ix.) about 0.1% w/v phenylephrine;
x.) about 10% w/v propylene glycol;
xi.) about 10% w/v polyethylene glycol; and
xii.) about 0.5% w/v polyvinylpyrrolidone

16. The liquid composition of Claim 15, wherein the composition comprises about 4% w/v guaifenesin and about 0.10% w/v phenylephrine, and the composition is visually free of guaifenesin precipitation for 14 days at -20°C.

17. The composition of Claim 15, wherein the composition is visually free of guaifenesin precipitation for at least 62 days at 4°C.

18. The liquid oral pharmaceutical composition of Claim 15, wherein the composition comprises about less than 2% total phenylephrine degradants, as a percent weight

over weight phenylephrine, and about less than 2% loss of phenylephrine from the initial total phenylephrine content, measured over a 3 month time period while stored at 40°C and 75% relative humidity.

19. A process for preparing an oral liquid composition, comprising the steps of:
a.) mixing until dissolved from about 0.1% to about 20% w/v of polyvinylpyrrolidone in an aqueous phase;
b.) adding and mixing from about 1% to about 20% w/v of at least one pharmaceutical agent;
c.) subsequently adding and mixing:
i.) water;
ii.) from about 1% to about 30% w/v of a propylene glycol;
iii.) from about 5% to about 70% w/v of a polyethylene glycol; and
d.) subsequently adding and mixing one or more additional ingredients.

20. The process of claim 17 wherein the composition comprises about less than 2% total phenylephrine degradants, as a percent weight over weight phenylephrine, and about less than 2% loss of phenylephrine from the initial total phenylephrine content, measured over a 3 month time period while stored at 40°C and 75% relative humidity.

21. The process of Claim 17, wherein the composition is visually free of guaifenesin precipitation for at least 62 days at 4°C.

22. A process for preparing a composition with reduced precipitation of a first pharmaceutical agent in combination with at least one or more second pharmaceutical agent(s) in an aqueous phase, wherein the composition comprises about less than 2% total phenylephrine degradants, as a percent weight over weight phenylephrine, and about less than 2% loss of phenylephrine from the initial total phenylephrine content, measured over a 3 month time period while stored at 40°C and 75% relative humidity, comprising the steps of:

a.) mixing until dissolved from about 0.1% to about 20% w/v of a polyvinylpyrrolidone in an aqueous solution;

b.) adding and mixing from about 1% to about 20% w/v of at least one pharmaceutical agent;

c.) subsequently adding and mixing:

i.) water;

ii.) from about 1% to about 10% w/v of a propylene glycol,

iii.) from about 10% to about 70% w/v of a polyethylene glycol; and

d.) subsequently adding and mixing one or more additional ingredients.

Claims

1. A liquid oral pharmaceutical composition comprising:

i.) from about 0.1 % to about 20% w/v polyvinylpyrrolidone;

ii.) from about 5% to about 70% w/v polyethylene glycol;

iii.) from about 1% to about 30% w/v propylene glycol;

iv.) from about 1% to 10% w/v guaifenesin; and

v.) from about 0.01 % to about 1.0% w/v phenylephrine,

wherein the composition is visually free of guaifenesin precipitation for at least 62 days at 4° C.

2. A liquid oral pharmaceutical composition comprising:

i.) from about 0.1 % to about 20% w/v polyvinylpyrrolidone;

ii.) from about 5% to about 70% w/v polyethylene glycol;

iii.) from about 1% to about 30% w/v propylene glycol;

iv.). from about 1% to 10% w/v guaifenesin; and

v.) from about 0.01% to about 1.0% w/v phenylephrine,

further comprising about 4% w/v guaifenesin and about 0.10% w/v phenylephrine, wherein the composition is visually free of guaifenesin precipitation for 14 days at -20° C.

3. A liquid oral pharmaceutical composition comprising:

i.) from about 0.1 % to about 20% w/v polyvinylpyrrolidone;

ii.) from about 5% to about 70% w/v polyethylene glycol;

iii.) from about 1 % to about 30% w/v propylene glycol;

iv.) from about 1 % to 10% w/v guaifenesin; and

v.) from about 0.01 % to about 1.0% w/v phenylephrine,

wherein the composition comprises about 4% w/v guaifenesin and about 0.10% w/v phenylephrine, about less than 2% total phenylephrine degradants, as a percent weight over weight phenylephrine, and about less than 2% loss of phenylephrine

from the initial total phenylephrine content, measured over a 3 month time period while stored at 40° C and 75% relative humidity.

4. A process for preparing an oral liquid composition, comprising the steps of:
    a.) mixing until dissolved from about 0.1% to about 20% w/v of polyvinylpyrrolidone in an aqueous phase;
    b.) adding and mixing from about 1% to about 20% w/v of at least one pharmaceutical agent;
    c.) subsequently adding and mixing:
        i.) water;
        ii.) from about 1% to about 30% w/v of a propylene glycol;
        iii.) from about 5% to about 70% w/v of a polyethylene glycol; and
    d.) subsequently adding and mixing one or more additional ingredients.

5. The process of claim 4 wherein the composition comprises about less than 2% total phenylephrine degradants, as a percent weight over weight phenylephrine, and about less than 2% loss of phenylephrine from the initial total phenylephrine content, measured over a 3 month time period while stored at 40° C and 75% relative humidity.

6. The process of Claim 4, wherein the composition is visually free of guaifenesin precipitation for at least 62 days at 4° C.