Abstract:

Title: PHENYLEPHRINE FORMULATIONS WITH IMPROVED STABILITY

A pharmaceutical composition includes a pharmaceutical polysaccharide and phenylephrine hydrochloride. The ratio of said polysaccharide to phenylephrine hydrochloride is sufficient to dilute the composition such that phenylephrine hydrochloride is stable at high temperature and humidity.
1. A composition comprising
   a pharmaceutical polysaccharide and phenylephrine hydrochloride;
   wherein the ratio of said polysaccharide to phenylephrine hydrochloride is sufficient to
dilate the composition such that phenylephrine hydrochloride is stable at high temperature and
humidity; and wherein the weight ratio of phenylephrine hydrochloride to polysaccharide is equal
to or between 1:20 and 1:60.

2. The composition of claim 1 wherein the weight ratio of phenylephrine hydrochloride to
   polysaccharide is 1:20.

3. The composition of claim 1 wherein the weight ratio of phenylephrine hydrochloride to
   polysaccharide is at least 1:30.

4. The composition of claim 1 wherein the weight ratio of phenylephrine hydrochloride to
   polysaccharide is at least 1:40.

5. The composition of claim 1 wherein the polysaccharide is maltodextrin.

6. The composition of claim 5 wherein the weight ratio of phenylephrine hydrochloride to
   maltodextrin is 1:20.

7. The composition of claim 5 wherein the weight ratio of phenylephrine hydrochloride to
   maltodextrin is at least 1:30.

8. The composition of claim 5 wherein the weight ratio of phenylephrine hydrochloride to
   maltodextrin is at least 1:40.
9. The composition of claim 1 comprising 650 mg acetaminophen, 25 mg diphenhydramine hydrochloride, 10 mg phenylephrine hydrochloride, and 312 mg maltodextrin per dose.

10. The composition of claim 1 comprising 650 mg acetaminophen, 25 mg dextromethorphan hydrobromide, 10 mg phenylephrine hydrochloride and 456 mg maltodextrin per dose.

11. The composition of claim 1 comprising 650 mg acetaminophen, 20 mg pheniramine maleate, 10 mg phenylephrine hydrochloride, 400-600 mg maltodextrin, and 50 mg ascorbic acid.

12. The composition of any of claims 1 to 11 wherein when the composition is exposed to a temperature of 30°C and 70% relative air humidity for 24 months, at least 95% of the original amount of phenylephrine hydrochloride is still present in the composition.

13. The composition of any of claims 1 to 12 wherein the composition is processed by a roller compactor-mill-sieve equipment train.

14. A method of making a composition according to any of claims 1 to 13 comprising combining a pharmaceutical polysaccharide and phenylephrine hydrochloride; and mixing to form a pharmaceutical composition; wherein the amount of the polysaccharide is sufficient to dilute the phenylephrine hydrochloride such that phenylephrine hydrochloride is stable at high temperature and humidity, and wherein the weight ratio of phenylephrine hydrochloride to polysaccharide is equal to or between 1:20 and 1:60.

15. The method of claim 14 wherein the polysaccharide is maltodextrin.

16. The method of claim 15 wherein the weight ratio of phenylephrine hydrochloride to maltodextrin is 1:20.
17. The method of claim 15 wherein the weight ratio of phenylephrine hydrochloride to maltodextrin is at least 1:30.

18. The method of claim 15 wherein the weight ratio of phenylephrine hydrochloride to maltodextrin is at least 1:40.

19. The method of claim 14 wherein the weight ratio of phenylephrine hydrochloride to polysaccharide is 1:20.

20. The method of claim 14 wherein the weight ratio of phenylephrine hydrochloride to polysaccharide is at least 1:30.

21. The method of claim 14 wherein the weight ratio of phenylephrine hydrochloride to polysaccharide is at least 1:40.

22. The method of claim 14 wherein the tableting composition comprises 650 mg acetaminophen, 25 mg diphenhydramine hydrochloride, 10 mg phenylephrine hydrochloride and 312 mg maltodextrin per dose.

23. The method of claim 14 wherein the tableting composition comprises 650 mg acetaminophen, 20 mg dextromethorphan hydrobromide, 10 mg phenylephrine hydrochloride and 456 mg maltodextrin per dose.

24. The method of claim 14 wherein the tableting composition comprises 650 mg acetaminophen, 20 mg pheniramine maleate, 10 mg phenylephrine hydrochloride, 400-600 mg maltodextrin, and 50 mg ascorbic acid.