Claims

1. An oral pharmaceutical fixed dose composition for the treatment of tuberculosis, wherein the oral pharmaceutical fixed dose composition is in the form of a dispersible bilayer tablet consisting essentially of:

a) isoniazid layer comprising isoniazid granules and at least one intragranular excipient;

b) rifapentine layer comprising rifapentine granules and at least one intragranular excipient; and

c) at least one extragranular excipient;

wherein the ratio of rifapentine to isoniazid is from 3:1 to 1:0.5.

2. The oral pharmaceutical fixed dose composition according to claim 1, wherein the oral fixed dose pharmaceutical composition is chemically stable.

3. A process for preparing the oral pharmaceutical fixed dose composition according to claim 1, comprising distinct steps of granulating isoniazid and granulating rifapentine.

4. The process according to claim 3, wherein the isoniazid granules and the rifapentine granules are made by wet granulation.

5. The process according to claim 3, comprising the steps of:

a) preparing the isoniazid granules;

b) preparing the rifapentine granules;

c) mixing the isoniazid granules and the rifapentine granules obtained from steps a) and

b) with the at least one extragranular excipient to form a mixture; and

d) compressing the mixture obtained from step c) to obtain a dispersible tablet.

6. The process according to claim 3, comprising the steps of:

a) preparing the isoniazid granules;

b) mixing the isoniazid granules obtained from step a) with at least one portion of the at least one extragranular excipient to form a first mixture;

c) preparing the rifapentine granules;

d) mixing the rifapentine granules obtained from step c) with a second portion of the at least one extragranular excipient to form a second mixture; and

e) compressing the first mixture of step b) and the second mixture of step d) to obtain a dispersible bilayer tablet.

7. The oral pharmaceutical fixed dose composition according to claim 1, wherein the ratio of rifapentine to isoniazid is 1:1.

8. The oral pharmaceutical fixed dose composition according to claim 1, wherein the ratio of rifapentine to isoniazid is 1:1.

9. The process of claim 3, wherein the ratio of rifapentine to isoniazid is 1:1.

10. The process of claim 5, wherein the ratio of rifapentine to isoniazid is 1:1.

11. The process of claim 6, wherein the ratio of rifapentine to isoniazid is 1:1.

12. The process of claim 4, wherein the isoniazid granules and the rifapentine granules are made by wet granulation in an aqueous solvent.

13. The process of claim 5, wherein the isoniazid granules and the rifapentine granules are made by wet granulation.

14. The process of claim 13, wherein the isoniazid granules and the rifapentine granules are made by wet granulation in an aqueous solvent.

15. The process of claim 6, wherein the isoniazid granules and the rifapentine granules are made by wet granulation.

16. The process of claim 15, wherein the isoniazid granules and the rifapentine granules are made by wet granulation in an aqueous solvent.

17. The process of claim 9, wherein the isoniazid granules and the rifapentine granules are made by wet granulation.

18. The process of claim 17, wherein the isoniazid granules and the rifapentine granules are made by wet granulation in an aqueous solvent.

19. The process of claim 10, wherein the isoniazid granules and the rifapentine granules are made by wet granulation.

20. The process of claim 19, wherein the isoniazid granules and the rifapentine granules are made by wet granulation in an aqueous solvent.

21. The process of claim 11, wherein the isoniazid granules and the rifapentine granules are made by wet granulation.

22. The process of claim 21, wherein the isoniazid granules and the rifapentine granules are made by wet granulation in an aqueous solvent.