standard and ibuprofen lysinate for C_{max} and AUC with a slightly faster T_{max}. In addition, this study found that sodium ibuprofen was bioequivalent to conventional ibuprofen for AUC, but was absorbed faster (higher C_{max} and faster T_{max}). Since this other formulation of sodium ibuprofen also provided faster onset of analgesia than standard ibuprofen tablets, these data suggest that the sodium ibuprofen tablets tested in the present study may provide an onset of analgesia faster than standard ibuprofen tablets, and at least as fast as the reference standard.

The three sodium ibuprofen prototype formulations and the reference standard evaluated in this pilot study were all well tolerated.

The present invention is not to be limited in scope by the specific embodiments described herein. Indeed, various modifications of the invention in addition to those described herein will become apparent to those skilled in the art from the foregoing description and the accompanying figures. Such modifications are intended to fall within the scope of the appended claims.

It is further to be understood that all values are approximate, and are provided for in the description.

CLAIMS:

1. A pharmaceutical composition comprising a core, said core comprising sodium ibuprofen, said composition having low sodium content.

2. The pharmaceutical composition according to claim 1, in the form of a tablet or caplet further comprising at least one coating.

3. A pharmaceutical composition comprising a core, said core comprising sodium ibuprofen, said composition having a ratio of sodium ibuprofen to total sodium content of about 11:1.

4. A pharmaceutical composition comprising a coated core, said core containing sodium ibuprofen, said coated core having a sodium content of less than 23 mg/dosage unit.

5. The pharmaceutical composition according to any one of claims 2-4, wherein the T_{max} of ibuprofen obtained by a human taking two such cores is about 40 minutes or less.

6. The pharmaceutical composition according to any one of claims 2-4, wherein the core further comprises at least one binder.

7. The pharmaceutical composition according to any one of claims 2-4, wherein the core further comprises at least two binders.

8. The pharmaceutical composition according to any one of claims 2-4, wherein the sodium ibuprofen of the tablet core is present in the form of a di-hydrate.

9. The pharmaceutical composition according to claim 8, wherein the sodium ibuprofen di-hydrate is present in an amount from 50 to 90% by weight, based on the weight of the core of the pharmaceutical composition.

10. The pharmaceutical composition according to claim 8, wherein the sodium ibuprofen di-hydrate is present in an amount from 60 to 80% by weight, based on the weight of the core of the pharmaceutical composition.

11. The pharmaceutical composition according to claim 8, wherein the sodium ibuprofen hydrate is present in an amount from 60 to 70% by weight, based on the weight of the core of the pharmaceutical composition.

12. The pharmaceutical composition according to any one of claims 2-4, further comprising one or more additional excipients in an amount from 0.1 to 20% by weight, based on the weight of the core of the pharmaceutical composition.

13. The pharmaceutical composition according to any one of claims 2-4, wherein the one or more pharmaceutically acceptable binders and other excipients are present in an amount from 10 to 50% by weight, based on the weight of the core of the pharmaceutical composition.

14. The pharmaceutical composition according to any one of claims 2-4, having a hardness of greater than 30 N.

15. The pharmaceutical composition according to any one of claims 2-4, having a hardness of greater than 40 N.

16. The pharmaceutical composition according to any one of claims 2-4, having a hardness of greater than 80 N.

17. The pharmaceutical composition according to any one of claims 2-4, wherein the one or more pharmaceutically acceptable coatings is present in an amount from 0.1 to 10% by weight, based on the weight of the core of the pharmaceutical composition.

18. A method of manufacturing a pharmaceutical composition comprising a core of sodium ibuprofen providing a low daily sodium content comprising the step of compressing the pharmaceutical composition into a core having a hardness greater than 30 N.

19. A method of manufacturing a pharmaceutical composition comprising a core containing sodium ibuprofen comprising the step of compressing the sodium ibuprofen and one or more excipients into a core and coating said core, said coated core having a hardness greater than 30 N., said coated core having a sodium content of less than 23 mg/dosage unit.

20. A method of manufacturing a pharmaceutical composition comprising a core, said core comprising sodium ibuprofen, said composition having a ratio of sodium ibuprofen to total sodium content of about 11:1.

21. The method according to claim 20, said composition provides a maximum daily sodium content of less than 140 mg/day.

22. The method according to claim 20, wherein the T_{max} of ibuprofen obtained by a human taking two such cores is about 40 minutes or less.

23. The method according to claims 20 or 22, the core further comprising at least one binder and at least one coating and the pharmaceutical composition in the form of a tablet or caplet.

24. The method according to claims 22 or 22, the core further comprising at least one binder.

25. The method according to claims 20 or 22, wherein the sodium ibuprofen of the core is present in the form of a di-hydrate.

26. The method according to claim 25, wherein the sodium ibuprofen di-hydrate is present in an amount from 50 to 90% by weight, based on the weight of the core of the pharmaceutical composition.

27. The method according to claim 25, wherein the sodium ibuprofen di-hydrate is present in an amount of at least 60 to 90% by weight, based on the weight of the core of the pharmaceutical composition.

28. The method according to claim 25, wherein the sodium ibuprofen di-hydrate is present in an amount from 60 to 80% by weight, based on the weight of the core of the pharmaceutical composition.

29. The method according to claims 22 or 24, the compressed composition having a hardness greater than 40 N.

30. The method according to claims 22 or 24, the compressed composition having a hardness greater than 80 N.

31. The method according to claims 22 or 24, wherein the amount of pharmaceutically acceptable one or more binders and other excipients is present in an amount from 10 to 50% by weight, based on the core of the pharmaceutical composition.

32. The method according to claims 22 or 24, wherein the one or more pharmaceutically acceptable coatings is present in an amount from 0.1 to 10% by weight, based on the weight of the core of the pharmaceutical composition.

33. A pharmaceutical composition comprising a sodium ibuprofen core wherein the T_{max} of ibuprofen obtained by a human taking an equivalent amount of 400 mg of ibuprofen is about 40 minutes or less.

34. A pharmaceutical composition according to claim 33 having a hardness of greater than 40 N.

5

CLAIMS:

1. A pharmaceutical composition comprising a core, said core comprising sodium ibuprofen dihydrate, mannitol, at least one disintegrants comprising microcrystalline cellulose, and at least one lubricant; wherein the sodium content of said pharmaceutical composition is below 140 mg per 1200 mg of free ibuprofen; wherein the disintegration time of said core is no greater than 5.48 minutes; and wherein the friability measurement of a batch of said core is no greater than 0.55%.

2. The pharmaceutical composition according to claim 1, in the form of a tablet or caplet further comprising at least one coating.

3. A pharmaceutical composition comprising a core, said core comprising sodium ibuprofen dihydrate, mannitol, at least one disintegrant comprising microcrystalline cellulose and at least one lubricant; said composition having a ratio of sodium ibuprofen dihydrate to total sodium content of about 11:1 by weight; wherein the disintegration time of said core is no greater than 5.48 minutes; and wherein the friability measurement of a batch of said core is no greater than 0.55%.

4. A pharmaceutical composition comprising a coated core, said core containing sodium ibuprofen dihydrate, mannitol, at least one disintegrant comprising microcrystalline cellulose and at least one lubricant; said coated core having a sodium content of less than 23 mg; wherein the disintegration time of said core is no greater than 5.48 minutes; and wherein the friability measurement of a batch of said core is no greater than 0.55%.

5. The pharmaceutical composition according to any one of claims 2-4, wherein the core further comprises at least one binder.

6. The pharmaceutical composition according to any one of claims 2-4, wherein the core further comprises at least two binders.

7. The pharmaceutical composition according to claim 2, wherein the sodium ibuprofen dihydrate is present in an amount from 50 to 90% by weight, based on the weight of the core of the pharmaceutical composition.

8. The pharmaceutical composition according to claim 2, wherein the sodium ibuprofen dihydrate is present in an amount from 60 to 80% by weight, based on the weight of the core of the pharmaceutical composition.

9. The pharmaceutical composition according to claim 2, wherein the sodium ibuprofen dihydrate is present in an amount from 60 to 70% by weight, based on the weight of the core of the pharmaceutical composition.

10. The pharmaceutical composition according to any one of claims 2-4, further comprising one or more additional excipients in an amount from 0.1 to 20% by weight, based on the weight of the core of the pharmaceutical composition.

11. The pharmaceutical composition according to any one of claims 2-4, having a hardness of greater than 30 N.

12. The pharmaceutical composition according to any one of claims 2-4, having a hardness of greater than 40 N.

13. The pharmaceutical composition according to any one of claims 2-4, having a hardness of greater than 80 N.