CLAIMS

1. A liquid aqueous oral pharmaceutical composition comprising nepadutant as active ingredient and an additive and a chelating agent, characterized in that the selected additive is *d-alpha tocopheryl polyethylene glycol 1000 succinate* (TPGS).

2. The pharmaceutical composition according to claim 1, wherein nepadutant is present in an amount from 0.01% to 1% weight/volume of the total composition.

3. The aqueous pharmaceutical composition according to claim 2, wherein nepadutant is present in an amount from 0.025% to 0.5% weight/volume on the total composition.

4. The aqueous pharmaceutical composition according to any one of claims 1-3, wherein TPGS is present in an amount of at least 0.1% weight/volume of the total composition.

5. The aqueous pharmaceutical composition according to claim 4, wherein TPGS is present in an amount from 0.1% to 20% weight/volume on the total composition.

6. The aqueous pharmaceutical composition according to claim 5, wherein TPGS is present in an amount from 0.5% to 5% weight/volume of the total composition.

7. The aqueous pharmaceutical composition according to any one of claims from 1 to 6, wherein the ratio between nepadutant and TPGS is from 1:1 to 1:50.

8. The aqueous pharmaceutical composition according to any one of claims from 1 to 7, wherein the ratio between nepadutant and TPGS is from 1:2 to 1:40.

9. The aqueous pharmaceutical composition according to any one of claims from 1 to 8, wherein the ratio between nepadutant and TPGS is from 1:4 to 1:30.

10. The aqueous pharmaceutical composition according to any one of claims from 1 to 9, wherein the chelating agent is selected from the group: EDTA, edetate disodium, and edetate calcium disodium.

11. The aqueous pharmaceutical composition according to claim 10, wherein the chelating agent is present in an amount comprised from 0.001% to 0.1% w/v of the total composition.

12. The aqueous pharmaceutical composition according to claim 11, wherein the chelating agent is present in an amount comprised from 0.005 % to 0.05 % w/v of the total composition.

13. The aqueous pharmaceutical composition according to claim 11, wherein the cheating agent is present in an amount comprised from 0.005% to 0.02% w/v of the total composition.

14. The aqueous pharmaceutical composition according to any one of claims from 1 to 13, further comprising pharmaceutical acceptable excipients selected from sweeteners, preservatives, or solubilizers.

15. The liquid aqueous oral pharmaceutical composition according to any one of claims from 1 to 14, comprising:

a) from 0.01% to 1% w/v of nepadutant

b) from 0.1% to 20% w/v of TPGS

c) optionally from 0.001% to 0.1% w/v of chelating agent

d) one or more pharmaceutically acceptable excipients selected from sweeteners, preservatives, or solubilizers.

16. The aqueous oral pharmaceutical composition according to claim 14, selected from the group:

a) nepadutant 0.40 mg/ml, TPGS 10.00 mg/ml, edetate disodium 0.100 mg/ml, dextrose 400.00 mg/ml, sorbic acid 1.00 mg/ml, sodium carboxymethylcellulose 20:00 mg / ml, purified water qs 1.0 ml;

b) nepadutant 2.00 mg/ml, TPGS 10.00 mg/ml, edetate disodium 0.100 mg/ml, dextrose 400.00 mg/ml, sorbic acid 1.00 mg/ml, sodium carboxymethylcellulose 20.00 mg/ml, purified water qs 1.0 ml.

17. The use of the aqueous oral pharmaceutical composition according to any one of claims 1 to 16 for the manufacture of a medicament for the paediatric treatment of gastrointestinal diseases.

18. A process for the preparation of the compositions according to any one of claims from 1 to 17, comprising a step wherein nepadutant is mixed with TPGS, and with a chelating agent.

CLAIMS

1. A liquid aqueous oral pharmaceutical composition comprising nepadutant as active ingredient and an additive and a chelating agent, characterized in that the selected additive is TPGS.

2. The liquid aqueous oral pharmaceutical composition according to claim 1, wherein nepadutant is present in an amount from 0.01% to 1% weight/volume of the total composition.

3. The liquid aqueous oral pharmaceutical composition according to claim 2, wherein nepadutant is present in an amount from 0.025% to 0.5% weight/volume on the total composition.

4. The liquid aqueous oral pharmaceutical composition according to any one of claims 1-3, wherein TPGS is present in an amount of at least 0.1% weight/volume of the total composition.

5. The liquid aqueous oral pharmaceutical composition according to claim 4, wherein TPGS is present in an amount from 0.1% to 20% weight/volume on the total composition.

6. The liquid aqueous oral pharmaceutical composition according to claim 5, wherein TPGS is present in an amount from 0.5% to 5% weight/volume of the total composition.

7. The liquid aqueous oral pharmaceutical composition according to any one of claims from 1 to 6, wherein the ratio between nepadutant and TPGS is from 1:1 to 1:50.

8. The liquid aqueous oral pharmaceutical composition according to any one of claims from 1 to 7, wherein the ratio between nepadutant and TPGS is from 1:2 to 1:40.

9. The liquid aqueous oral pharmaceutical composition according to any one of claims from 1 to 8, wherein the ratio between nepadutant and TPGS is from 1:4 to 1:30.

10. The liquid aqueous oral pharmaceutical composition according to any one of claims from 1 to 9, wherein the chelating agent is selected from the group: EDTA, edetate disodium, and edetate calcium disodium.

11. The liquid aqueous oral pharmaceutical composition according to claim 10, wherein the chelating agent is present in an amount comprised from 0.001% to 0.1% w/v of the total composition.

12. The liquid aqueous oral pharmaceutical composition according to claim 11, wherein the chelating agent is present in an amount comprised from 0.005 % to 0.05 % w/v of the total composition.

13. The liquid aqueous oral pharmaceutical composition according to claim 11, wherein the cheating agent is present in an amount comprised from 0.005% to 0.02% w/v of the total composition.

14. The liquid aqueous oral pharmaceutical composition according to any one of claims from 1 to 13, further comprising pharmaceutical acceptable excipients selected from sweeteners, preservatives, or solubilizers.

15. The liquid aqueous oral pharmaceutical composition according to any one of claims from 1 to 14, comprising:

a) from 0.01% to 1% w/v of nepadutant

b) from 0.1% to 20% w/v of TPGS

c) from 0.001% to 0.1% w/v of chelating agent

d) one or more pharmaceutically acceptable excipients selected from sweeteners, preservatives, or solubilizers.

16. The liquid aqueous oral pharmaceutical composition according to claim 14, selected from the group:

a) nepadutant 0.40 mg/ml, TPGS 10.00 mg/ml, dextrose 400.00 mg/ml, sorbic acid 1.00 mg/ml, sodium carboxymethyl cellulose 20.00 mg/ml, purified water qs 1.0 ml;

b) nepadutant 0.40 mg/ml, TPGS 10.00 mg/ml, edetate disodium 0.100 mg/ml, dextrose 400.00 mg/ml, sorbic acid 1.00 mg/ml, sodium carboxymethylcellulose 20:00 mg / ml, purified water qs 1.0 ml;

c) nepadutant 2.00 mg/ml, TPGS 10.00 mg/ml, edetate disodium 0.100 mg/ml,

dextrose 400.00 mg/ml, sorbic acid 1.00 mg/ml, sodium carboxymethylcellulose 20.00 mg/ml, purified water qs 1.0 ml.

17. Use of the liquid aqueous oral pharmaceutical composition according to any one of claims 1 to 16 for the manufacture of a medicament for paediatric treatment.

18. The use according to claim 17 for the manufacture of a medicament for the

paediatric treatment of gastrointestinal diseases.

19. A process for the preparation of the liquid aqueous oral pharmaceutical compositions according to any one of claims from 1 to 16, comprising a step wherein nepadutant is mixed with TPGS, and with a chelating agent.