27. The sustained release formulation according to claim 16, wherein the sustained release formulation is a bilayer tablet having a sustained release phase in one layer and an immediate release phase in one layer.

28. The sustained release formulation according to claim 16, wherein the sustained release formulation is a monolayer tablet.

29. The sustained release formulation according to claim 16, wherein the ratio of high viscosity hypromellose to low viscosity hypromellose is 3:1.

30. A sustained release formulation containing 1000mg paracetamol present in a sustained release phase and an immediate release phase in which the ratio of the paracetamol in the sustained release phase to the immediate release phase is about 80-90% to 10-20% and wherein the sustained release phase comprises from 0.5% to 3% w/w of a pre-gelatinized starch and a matrix forming polymer of hydroxypropylmethyl cellulose, wherein the hydroxypropylmethyl cellulose contains from 4% to 6% by weight of a high viscosity hydroxypropylmethyl cellulose having a viscosity between 3500 and 6000 centipoise and from 1% to 2% by weight of a low viscosity hydroxypropylmethyl cellulose having a viscosity between 10 and 30 centipoise , and which when ingested by a human reduces maximum attained plasma-paracetamol concentration (C_{max}) by at least about 4.5% at steady state (relative to rapid-release paracetamol formulations), and increases time to reach maximum paracetamol-plasma concentration (T_{max}) by at least about 140% at steady state (relative to rapid-release paracetamol formulations), while having an insignificant effect on area under the plasma-paracetamol concentration time curve $AUC_{(0-24)}$; mean $AUC_{(0-24)}$ of about 165 µg*h/ml for sustained release paracetamol at steady state (2000mg dosed every 12 hours) versus a mean $AUC_{(0-24)}$ of about 168 µg*h/ml for 1000mg immediate release at steady state (dosed every 6 hours) and wherein the formulation is repeatedly administered (steady state).

31. The sustained release formulation according to any of the preceding claims which has the following *in vitro* bio-dissolution profile of the dissolution release ranges at various time points (as determined by USP Type II apparatus, rotating paddle, with 900 ml of Phosphate buffer at pH 7.4, 37 °C set at rotating speed of 75rpm) of:

- 2 to 15% released at 15 minutes;
- 4 to 22% released at 30 minutes;
- 10 to 40% released at 60 minutes;
- 22 to 62% released at 180 minutes
- 50 to 88% released at 360 minutes;
- >90% released after 720 minutes.

32. A sustained release formulation of paracetamol administered in two tablets each tablet having a sustained release phase and an immediate release phase of paracetamol with the following characteristics in a human upon oral administration of one single dose:

- a plasma level of paracetamol which has a minimum duration time above the mean of at least 5μg/ml for about 6 hours after a single dose;
- a plasma level of paracetamol which has a minimum duration time above the mean of at least 4μg/ml for about 8 hours after a single dose;
- a plasma level of paracetamol which has a minimum duration time above the mean of at least 3μg/ml for about 10 hours after a single dose;
- wherein the mean $AUC_{(0-\infty)}$ is about 85 μg*h/ml to about 120 μg*h/ml;
- wherein the mean $AUC_{(0-24)}$ is about 64 μg*h/ml to about 124 μg*h/ml;
- wherein the mean $AUC_{(0-6)}$ is about 38 μg*h/ml to about 40 μg*h/ml; and
- wherein the 90% confidence intervals for the ratios of the extend release formulation/conventional immediate release formulation and the extend release formulation/8 hours extend formulation for all three pharmacokinetic parameters AUC(0-∞), AUC(0-t), and C_{max} all lie within the bioequivalence boundaries [0.80, 1.25]; and
- the amount of paracetamol administered is 2000mg, as compared to an equivalent amount of immediate release paracetamol.

33. The use of a sustained release formulation comprising about 2000mg paracetamol present in a sustained release phase of paracetamol and an

immediate release phase of paracetamol, in the manufacture of a medicament for the treatment of analgesia or pain, wherein said dosage form has the following *in vitro* bio-dissolution profile of the dissolution release ranges at various time points (as determined by USP Type II apparatus, rotating paddle, with 900 ml of Phosphate buffer at pH 7.4, 37°C set at rotating speed of 75rpm) of:

- 2 to 15% released at 15 minutes;
- 4 to 22% released at 30 minutes;
- 10 to 40% released at 60 minutes;
- 22 to 62% released at 180 minutes
- 50 to 88% released at 360 minutes;
- >90% released after 720 minutes, and
- wherein said formulation provides a therapeutically effective plasma concentration over a 12 hours period to treat analgesia or pain.

27. The sustained release formulation according to claim 16, wherein the sustained release formulation is a bilayer tablet having a sustained release phase in one layer and an immediate release phase in one layer.

28. The sustained release formulation according to claim 16, wherein the sustained release formulation is a monolayer tablet.

29. The sustained release formulation according to claim 16, wherein the ratio of high viscosity hypromellose to low viscosity hypromellose is 3:1.

30. A sustained release formulation containing 1000mg paracetamol present in a sustained release phase and an immediate release phase in which the ratio of the paracetamol in the sustained release phase to the immediate release phase is about 80-90% to 10-20% and wherein the sustained release phase comprises from 0.5% to 3% w/w of a pre-gelatinized starch and a matrix forming polymer of hydroxypropylmethyl cellulose, wherein the hydroxypropylmethyl cellulose contains from 4% to 6% by weight of a high viscosity hydroxypropylmethyl cellulose having a viscosity between 3500 and 6000 centipoise and from 1% to 2% by weight of a low viscosity hydroxypropylmethyl cellulose having a viscosity between 10 and 30 centipoise , and which when ingested by a human reduces maximum attained plasma-paracetamol concentration (C_{max}) by at least about 4.5% at steady state (relative to rapid-release paracetamol formulations), and increases time to reach maximum paracetamol-plasma concentration (T_{max}) by at least about 140% at steady state (relative to rapid-release paracetamol formulations), while having an insignificant effect on area under the plasma-paracetamol concentration time curve $AUC_{(0-24)}$; mean $AUC_{(0-24)}$ of about 165 μg*h/ml for sustained release paracetamol at steady state (2000mg dosed every 12 hours) versus a mean $AUC_{(0-24)}$ of about 168 μg*h/ml for 1000mg immediate release at steady state (dosed every 6 hours) and wherein the formulation is to be repeatedly administered (steady state).

31. A sustained release formulation for oral administration containing 2000mg of paracetamol administered in two tablets, each tablet having 1000mg of paracetamol

present in a sustained release phase and an immediate release phase, in which the ratio of the paracetamol in the sustained release phase to the immediate release phase is about 80-90% to 10-20%, and wherein the sustained release phase comprises from 0.5% to 3% w/w of a pre-gelatinized starch and a matrix forming polymer of hydroxypropylmethyl cellulose, wherein the hydroxypropylmethyl cellulose contains a high viscosity hydroxypropylmethyl cellulose having a viscosity between 3500 and 6000 centipoise present in an amount from 4% to 6% by weight of the sustained release phase of the formulation and a low viscosity hydroxypropylmethyl cellulose having a viscosity between 10 and 30 centipoise present in an amount from 1% to 2% by weight of the sustained release phase of the formulation which has the following *in vitro* bio-dissolution profile of the dissolution release ranges at various time points (as determined by USP Type II apparatus, rotating paddle, with 900 ml of Phosphate buffer at pH 7.4, 37 ^{o}C set at rotating speed of 75rpm) of:

- 2 to 15% released at 15 minutes;
- 4 to 22% released at 30 minutes;
- 10 to 40% released at 60 minutes;
- 22 to 62% released at 180 minutes
- 50 to 88% released at 360 minutes;
- >90% released after 720 minutes.

32. A sustained release formulation containing 2000mg of paracetamol administered in two tablets, each tablet having 1000mg of paracetamol present in a sustained release phase and an immediate release phase, in which the ratio of the paracetamol in the sustained release phase to the immediate release phase is about 80-90% to 10-20%, and wherein the sustained release phase comprises from 0.5% to 3% w/w of a pre-gelatinized starch and a matrix forming polymer of hydroxypropylmethyl cellulose, wherein the hydroxypropylmethyl cellulose contains a high viscosity hydroxypropylmethyl cellulose having a viscosity between 3500 and 6000 centipoise present in an amount from 4% to 6% by weight of the sustained release phase of the formulation and a low viscosity hydroxypropylmethyl cellulose having a viscosity between 10 and 30 centipoise present in an amount from 1% to 2% by weight of the

sustained release phase of the formulation with the following characteristics in a human upon oral administration of one single dose:

- a plasma level of paracetamol which has a minimum duration time above the mean of at least 5μg/ml for about 6 hours after a single dose;
- a plasma level of paracetamol which has a minimum duration time above the mean of at least 4μg/ml for about 8 hours after a single dose;
- a plasma level of paracetamol which has a minimum duration time above the mean of at least 3μg/ml for about 10 hours after a single dose;
- wherein the mean AUC $_{(0-\infty)}$ is about 85 μg*h/ml to about 120 μg*h/ml;
- wherein the mean AUC $_{(0-24)}$ is about 64 μg*h/ml to about 124 μg*h/ml;
- wherein the mean AUC $_{(0-6)}$ is about 38 μg*h/ml to about 40 μg*h/ml; and
- wherein the 90% confidence intervals for the ratios of the extend release formulation/conventional immediate release formulation and the extend release formulation/8 hours extend formulation for all three pharmacokinetic parameters AUC(0-∞), AUC(0-t), and C_{max} all lie within the bioequivalence boundaries [0.80, 1.25]; and
- the amount of paracetamol administered is 2000mg, as compared to an equivalent amount of immediate release paracetamol.

33. The use of a sustained release formulation comprising about 2000mg paracetamol present in a sustained release phase of paracetamol and an immediate release phase of paracetamol, in the manufacture of a medicament for the treatment of analgesia or pain, wherein said dosage form has the following *in vitro* bio-dissolution profile of the dissolution release ranges at various time points (as determined by USP Type II apparatus, rotating paddle, with 900 ml of Phosphate buffer at pH 7.4, 37°C set at rotating speed of 75rpm) of:
    - 2 to 15% released at 15 minutes;
    - 4 to 22% released at 30 minutes;
    - 10 to 40% released at 60 minutes;
    - 22 to 62% released at 180 minutes
    - 50 to 88% released at 360 minutes;

- >90% released after 720 minutes, and
- wherein said formulation provides a therapeutically effective plasma concentration over a 12 hours period to treat analgesia or pain.