CLAIMS

1. A polymer comprising of three monomeric units, selected from 1-Vinylpyrrolidone (VP), N-Isopropylacrylamide (NIPAM), and ester of Maleic anhydride and Polyethylene glycol (MPEG), cross-linked with a bi-functional vinyl derivative, of high purity and substantially free of respective toxic monomeric contaminants.

2. A polymer comprising of three monomeric units, selected from 1-Vinylpyrrolidone (VP), N-Isopropylacrylamide (NIPAM), and ester of Maleic anhydride and Polyethylene glycol (MPEG), cross-linked with a bi-functional vinyl derivative, of high purity, containing respective toxic monomeric contaminants in amounts less than 0.001%.

3. A polymer of high purity according to anyone of claims 1 and 2, wherein the bi-functional vinyl cross-linking agent is N,N'-Methylene bis acrylamide (MBA).

4. A polymer of high purity according to anyone of claims 1 and 2, containing toxic 1-Vinylpyrrolidone (VP) in amounts less than 0.001%.

5. A polymer of high purity according to anyone of claims 1 and 2, containing toxic N-Isopropylacrylamide (NIPAM) in amounts less than 0.001%.

6. A polymer according to anyone of claims 1 and 2, wherein the weight ratio of the monomers, NIPAM: VP is in the range of between 55:22 to 65: 35.

7. A polymer according to claim 6, wherein the weight ratio of the monomers, NIPAM: VP is in the range of between 58: 32 to 62: 28.

8. A polymer according to anyone of claims1 and 2, wherein the weight ratio of monomers, (NIPAM + VP): MPEG is in the range of between 90: 10 to 95: 5.

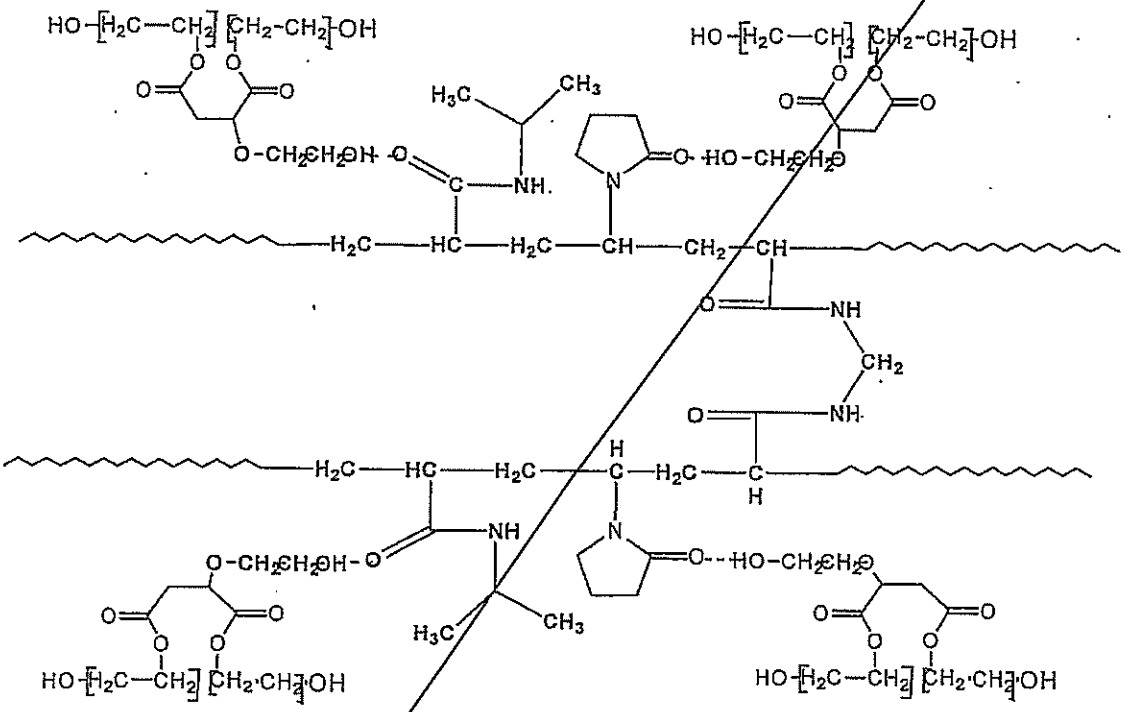
9. A polymer according to claim 8, wherein the weight ratio of monomers, (NIPAM + VP): MPEG is in the range of between 80:20 to 95:5.

10. A polymer according to anyone of claims1 and 2, having peaks of δ at 174, 76.6-77.6, 70.6, 41.6, 31.8 , and 22.6 in their ^{13}C NMR spectrum.

11. A polymer according to anyone of claims1 and 2, having peaks of δ at 1.14, 1.45, 1.63, 1.99, 2.36, 3.0, 3.23, 3.62-3.66, 3.72, and 3.97 in their ^{1}H NMR spectrum.

12. A polymer according to anyone of claims1 and 2, having frequency of values cm^{-1} at as 3500, 3296, 2972-2933, 1546, 1387, 1367, and 1172-1129 in their FT-IR spectrum.

13. A polymer according to anyone of claims1 and 2, having structure of formula (I),



(I)

14. A polymer according to anyone of claims1 and 2, which is biocompatible.

15. A polymer according to anyone of claims1 and 2, which is non-biodegradable.

16. A polymer according to anyone of claims 1and 2, which is non-toxic.

17. A polymer according to anyone of claims 1and 2, having a $T_{1/2}$ (K10) value of 0.152 ± 0.018 hours.

18. A polymer according to anyone of claims 1and 2, having $T_{1/2}$ (α) value of 0.065 ± 0.014 hours.

19. A polymer according to anyone of claims 1and 2, having a $T_{1/2}$ (β) value of 0.448 ± 0.0157 hours.

20. A polymer according to anyone of claims 1and 2, having a C_{max} value of 82.96 ± 5.11 µg/ml.

21. A polymer according to anyone of claims 1and 2, having an Area Under the Curve (AUC) value of 18.29 ± 1.62 hours x µg/ml.

22. A polymer according to anyone of claims 1and 2, having a Clearance Time (CL) value of 54.67 ± 4.86 ml/hr.

23. A polymer according to anyone of claims 1and 2, having a Mean Residence Time (MRT) value of 0.465 ± 0.13 hours.

24. A polymer according to anyone of claims 1and 2, having a Volume Distribution Under Steady State (V_{ss}) value of 25.43 ± 5.2 ml/hr.

25. A polymer according to anyone of claims 1and 2, which is eliminated from urine faeces, tissues, and rinse.

26. A polymer according to anyone of claims 1, 2 and 25, which is predominantly eliminated from urine and faeces.

27. A polymer according to anyone of claims 1, 2 and 25, about 67% of which is eliminated from urine 48 hours post dosing.

28. A polymer according to anyone of claims 1, 2 and 25, about 17% of which is eliminated from faeces 48 hours post dosing.

29. A polymer according to anyone of claims 1, 2 and 25, about 84% of which is eliminated from urine, faeces, tissues and rinse, 48 hours post dosing.

30. A polymer according to anyone of claims 1and 2, which does not cause any local toxicity at the site of administration, 48 hours post subcutaneous adminstration of an aqueous solution of the said polymer in a rabbit ear.

31. A polymer according to anyone of claims 1and 2, which does not cause any local toxicity at the site of administration, 24 hours post intravenous adminstration of an aqueous solution of the said polymer in a rabbit ear vein.

32. A polymer according to anyone of claims 1and 2, which does not cause any general toxicity, when administrated through an intravenous bolar route to Wistar rats up to five consecutive days at a dose of between 400 mg/kg to 800 mg/kg.

33. A polymer according to anyone of claims 1and 2, which does not cause any significant haematological toxicity, when administrated through an intravenous bolar route to Wistar rats up to five consecutive days at a dose of between 400 mg/kg to 800 mg/kg.

34. A [^{14}C]- labelled polymer comprising of three monomeric units, selected from 1-Vinylpyrrolidone (VP), N-Isopropylacrylamide (NIPAM), and ester of Maleic anhydride and Polyethylene glycol (MPEG), cross-lined with N,N'-Methylene bis acrylamide (MBA).

35. A [^{14}C]- labelled polymer comprising of three monomeric units, selected from 1-Vinylpyrrolidone (VP), N-Isopropylacrylamide (NIPAM), and ester of Maleic anhydride and Polyethylene glycol (MPEG), cross-lined with N,N'-Methylene bis acrylamide (MBA).

36. A [^{14}C]- labelled polymer of high purity according to anyone of claims 34 and 35, wherein the weight ratio of the monomers, NIPAM: VP is in the range of between 55:22 to 65: 35, and the ratio of monomers, (NIPAM + VP): MPEG is in the range of between 90: 10 to 95: 5.

37. A [^{14}C]- labelled polymer of high purity according to anyone of claims 34, 35 and 38 wherein the weight ratio of the monomers, NIPAM: VP is in the range of between 58: 32 to 62: 28, and the ratio of monomers, (NIPAM + VP): MPEG is in the range of between 80:20 to 95:5.

38. A process for preparation of a polymer of high purity and substantially free of respective toxic monomeric contaminants and containing respective toxic monomeric contaminants in amounts less than 0.001%, according to claims 1 and 2 comprising the steps of:

i) Dissolving appropriate quantities of the three monomers, NIPAM, VP and MPEG in water;

ii) Adding in succession to the solution of step i), appropriate quantities of a cross-linking agent and an activator;

iii) Bubbling an inert gas into the solution of step ii) for a period of between 30 to 60 minutes;

iv) Adding an appropriate quantity of an activator and a polymerization initiator to the solution of step iv);

v) Polymerization of the solution of step iv), at a temperature of between 25^0 C to 45^0 C, under an atmosphere of an inert gas for 3 to 6 hours;

vi) Subjecting the solution of step v) to filtration through pre-sterilized filters and collecting the filtrate;

vii) Subjecting the filtrate of step vi) to diafiltration and collecting the filtrate;

viii) Optionally subjecting the filtrate of step vii) to an additional step of diafiltration and collecting the filtrate; and

ix) Optionally subjecting the filtrate of step vii) or viii) to lyophilization to obtain a lyophilized powder of the polymer.

39. A process according to claim 38, wherein the ratio of the monomers, NIPAM: VP is in the range of between 55:22 to 65: 35, and the weight ratio of monomers, (NIPAM + VP): MPEG is in the range of between 90: 10 to 95: 5.

40. A process according to claim 38, wherein the weight ratio of the monomers, NIPAM: VP is in the range of between 58: 32 to 62: 28, and the ratio of monomers, (NIPAM + VP): MPEG is in the range of between 80:20 to 95:5.

41. A process according to claim 38, wherein the cross-linking agent is a bi-functional vinyl derivative.

42. A process according to claim 41, wherein the bi-functional vinyl derivative is N,N^1-methylene bis acrylamide.

43. A process according to claim 38, wherein the cross-linking agent is employed in quantities in the range of between 1.3 to 1.5 % w/w of the total monomer content.

44. A process according to claim 43, wherein the cross-linking agent is employed in quantities in the range of between 1.35 to 1.4 % w/w of the total monomer content.

45. A process according to claim 38, wherein the activator is selected from any one of Tetramethylethylene diamine or Ferrous Ammonium Sulphate, or a combination of both.

46. A process according to claim 38, wherein the activator is employed in quantities in the range of between 15 to 18 % w/w of the total monomer content.

47. A process according to claim 46, wherein the activator is employed in quantities in the range of between 15 to 16 % w/w of the total monomer content.

48. A process according to claim 38, wherein the polymerization initiator is at least one or more selected from peroxide compounds, such as diacyl peroxide, benzoyl peroxide, diacetyl peroxide, dialkyl peroxides, tertiary butyl peroxide and tertiary amyl peroxide or nitrile based polymerization initiators such as 2, 2'-Azobis isobutyronitrile (AIBN) or inorganic salt based polymerization initiators such as Ammonium perdisulphate or Ammonium persulphate.

49. A process according to claim 48, wherein the polymerization initiator is Ammonium perdisulphate or Ammonium persulphate.

50. A process according to claim 38, wherein the polymerization initiator is employed in quantities in the range of between 20 to 30 % w/w of the total monomer content.

51. A process according to claim 50, wherein the polymerization initiator is employed in quantities in the range of between 23 to 25 % w/w of the total monomer content.

52. A process according to claim 38, wherein the inert gas is argon or nitrogen.

53. A process according to claim 38, wherein the pre-sterilized filter utilized in step v) is a disposable 0.2μm Polyethersulphone membrane 1" capsule filters having a pore size of 0.8 and 0.2μm.

54. A process according to claim 38, wherein the diafiltration equipment utilized in steps vi) and vii) is a Proflux M12 diafiltration device of Millipore Make.

55. A polymer obtained by the process of claim 38, containing toxic 1-Vinylpyrrolidone (VP) less than 0.001%.

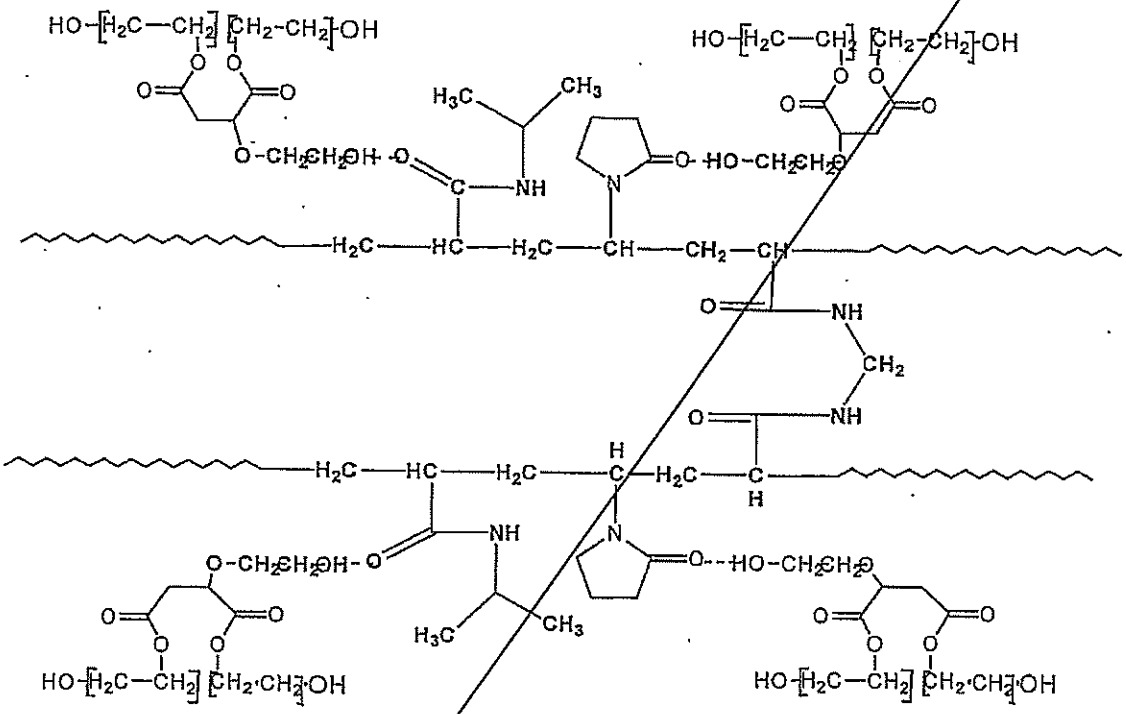
56. A polymer obtained by the process of claim 38, containing toxic N-Isopropylacrylamide (NIPAM) less than 0.001%.

57. A polymer obtained by the process of claim 38, having peaks of δ at 174, 76.6-77.6, 70.6, 41.6, 31.8 and 22.6 in its ^{13}C NMR spectrum.

58. A polymer obtained by the process of claim 38, having peaks of δ at 1.14, 1.45, 1.63, 1.99, 2.36, 3.0, 3.23, 3.62-3.66, 3.72, and 3.97 in its ^{1}H NMR spectrum.

59. A polymer obtained by the process of claim 38, having frequency of values cm^{-1} at as 3500, 3296, 2972-2933, 1546, 1387, 1367, and 1172-1129 in its FT-IR spectrum.

60. A polymer obtained by the process of claim 38, having structure of formula (I),



(I)

61. A polymer obtained by the process of claim 38, which is biocompatible, non-biodegradable and non-toxic.

62. A polymer obtained by the process of claim 38, having a $T_{1/2}$ (K10) value of 0.152 ± 0.018 hours; a $T_{1/2}$ (α) value of 0.065 ± 0.014 hours; a $T_{1/2}$ (β) value of 0.448 ± 0.0157 hours; a C_{max} value of 82.96 ± 5.11 µg/ml; an Area Under the Curve (AUC) value of 18.29 ± 1.62 hours x µg/ml; a Clearance Time (CL) value of 54.67 ± 4.86 ml/hr; a Mean Residence Time (MRT) value of 0.465 ± 0.13 hours; and a Volume Distribution Under Steady State (V_{ss}) value of 25.43 ± 5.2 ml/hr.

63. A polymer obtained by the process of claim 38, about 84% of which is eliminated from urine, faeces, tissues and rinse 48 hours post dosing.

64. A polymer obtained by the process of claim 38, which does not cause any local toxicity at the site of administration, 48 hours post subcutaneous adminstration of an aqueous solution of the said polymer in a rabbit ear or 24 hours post intravenous adminstration of an aqueous solution of the said polymer in a rabbit ear vein.

65. A polymer obtained by the process of claim 38, which does not cause any general toxicity or haematological toxicity, when administrated through an intravenous bolar route to Wistar rats up to five consecutive days at a dose of between 400 mg/kg to 800 mg/kg.

66. A kit comprising (a) a vial containing a solution of a poorly water-soluble drug or compound in a water-miscible solvent or mixtures thereof and (b) another vial containing a solution of a polymer of anyone of claims 1 and 2, of high purity and substantially free of monomeric contaminants and pharmaceutically acceptable excipients, wherein (a) and (b) are provided in a ratio of between 1: 1 to 1: 10 by volume, suitable for preparation of a pharmaceutical composition of the said poorly water-soluble drugs or compounds in nanoparticulate form for administration to patients in need thereof.

67. The kit according to claim 66 wherein poorly water-soluble drugs or compounds have solubility in water of less than 10 mg/ml.

68. The kit according to claim 66 wherein poorly water-soluble drug or compound, is selected from the class of anticancer agents, anti-inflammatory agents, anti-fungal agents, antiemetics, antihypertensive agents, sex hormones, steroids, antibiotics, anaesthetics or immunomodulators.

69. The kit according to claim 68 wherein anticancer agents are selected from Paclitaxel, Docetaxel, and other related taxane derivatives; Irinotecan, Topotecan, and other related Camptothecin derivatives; Doxorubicin, Daunomycin, and related Anthracycline derivatives; Cisplatin; Oxaliplatin; 5-Fluorouracil; Mitomycin; Methotrexate; Etoposide; Betulinic acid and its derivatives; and Wedelolactone and its derivatives.

70. The kit according to claim 68 wherein anti-inflammatory agents are selected from Indomethacin, Ibuprofen, Ketoprofen, Flubiprofen, Piroxicam, Tenoxicam, and Naproxen.

71. The kit according to claim 68 wherein anti-fungal agents are selected from Ketoconazole, and Amphotericin B.

72. The kit according to claim 68 wherein sex hormones are selected from Testosterone, Estrogen, Progesterone, and Estradiol.

73. The kit according to claim 68 wherein steroids are selected from Dexamethasone, Prednisolone, and Triamcinolone.

74. The kit according to claim 68 wherein antihypertensive agents are selected from Captopril, Ramipril, Terazosin, Minoxidil, and Parazosin.

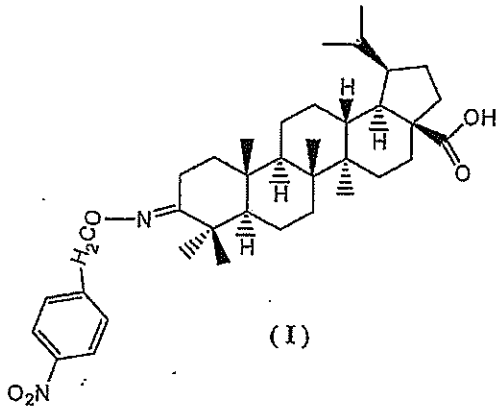
75. The kit according to claim 68 wherein antiemetics are selected from Ondansetron and Granisetron.

76. The kit according to claim 68 wherein antibiotics are selected from Metronidazole, and Fusidic acid.

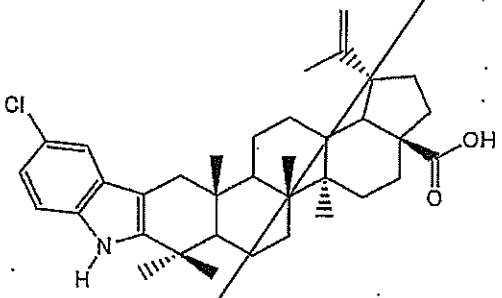
77. The kit according to claim 68 wherein immunomodulators are selected from Cyclosporine; and Biphenyl dimethyl dicarboxylic acid.

78. The kit according to claim 68 wherein anaesthetics are selected from Propolol, Alfaxalone, and Hexobarbital.

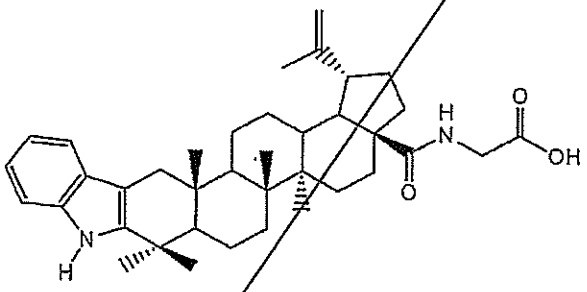
79. The kit according to claim 68 wherein the Betulinic acid derivatives are selected from MJ-1098 of formula (II), DRF-4012 of formula (III), and DRF-4015 of formula (IV).



(I)



(II)



(III)

80. The kit according to claim 66 wherein the water-miscible solvent, is selected from ethanol, dimethyl formamide, dimethyl acetamide, diemthyl sulfoxide, diethyl sulfoxide; polyethylene glycols of various molecular weights; polypropylene glycols of various molecular weights; polysorbate 80, polysorbate 20, polyoxyethylated vegetable oil, polyethoxylated castor oil or glycerine and mixtures thereof.

81. The kit according to claim 66 wherein the pharmaceutically acceptable excipients are selected from sodium deoxycholate; bile salts, polysorbate 80; polysorbate 20, polyoxyethylated vegetable oil; polyethoxylated castor oil; polysaccharides like dextrose, sucrose, lactose, and mannitol; sorbitan esters or spans of various grades, myrj of various grades, or poloxomers of various grades and mixtures thereof.

82. The kit according to claim 81 wherein the pharmaceutically acceptable excipients further comprises a buffering agent.

83. The kit according to claim 82 wherein the buffering agent is sodium citrate.

84. The kit according to claim 66 optionally comprising a diluting fluid, and a syringe and a needle having an internal diameter in the range of 0.305 to 0.356 mm, if a small volume, say 1-5 ml of the contents of vial a) are to be added to about 35 times its volume comprising the contents of vial b) in the diluting fluid or a syringe and a needle having an internal diameter in the range of 0.559 to 0.711 mm, if a larger volume, say 10-15 ml of the contents of vial a) are to be added to about 35 times its volume comprising the contents of vial b) in the diluting fluid.

85. A pharmaceutical composition in nanoparticulate form, comprising a poorly water-soluble drug or compound, a water-miscible solvent, a polymer according to anyone of claims 1 and 2, and pharmaceutically acceptable excipients, all of which are contained in a diluting fluid, suitable for adminstration to patients in need thereof.

86. A pharmaceutical composition according to claim 85 wherein the poorly water-soluble drugs are those as given in preceding claims 68-79.

87. A pharmaceutical composition according to claim 85 wherein the pharmaceutically acceptable excipients are those as given in the preceding claims 81-83.

88. A pharmaceutical composition according to claim 85 wherein the water-miscible solvents are those as given in the preceding claim 80.

89. A pharmaceutical composition according to claim 85 wherein the diluting fluid is selected from water, saline, dextrose 5% and 10% solutions, dextrose and sodium chloride solution, sodium lactate solution, lactated Ringer solution, mannitol solution, mannitol with dextrose or sodium chloride solution, Ringer's solution, sodium chloride solution, sterile water for injection and multiple electrolyte solutions comprising varying combinations of electrolytes, dextrose, fructose and invert sugar.

90. A pharmaceutical composition according to claim 85, wherein the poorly water-soluble drug or compound is entrapped within the polymeric shell in nanoparticulate form.

91. A pharmaceutical composition according to claim 90 wherein the particle size of the nanoparticulate form is in the range of between 30 to 150 nm.

92. A pharmaceutical composition according to claim 85, wherein the polymer utilized therein is of high purity; having structure of formula (I); containing monomeric VP and NIPAM in amounts less than 0.001%; having peaks of δ at 174, 76.6-77.6, 70.6, 41.6, 31.8 , and 22.6 in its ^{13}C NMR spectrum; having peaks of δ at 1.14, 1.45, 1.63, 1.99, 2.36, 3.0, 3.23, 3.62-3.66, 3.72, and 3.97 in its ^{1}H NMR spectrum; and having frequency of values cm^{-1} at as 3500, 3296, 2972-2933, 1546, 1387, 1367, and 1172-1129 in its FT-IR spectrum.

93. A pharmaceutical composition according to claim 85, wherein the polymer utilized therein is of high purity; having structure of formula (I); containing monomeric VP and NIPAM in amounts less than 0.001%; having a $T_{1/2}$ (K10) value of 0.152 ± 0.018 hours; a $T_{1/2}$ (α) value of 0.065 ± 0.014 hours; a $T_{1/2}$ (β) value of 0.448 ± 0.0157 hours; a C_{max} value of 82.96 ± 5.11 μg/ml; an Area Under the Curve (AUC) value of 18.29 ± 1.62 hours x μg/ml; a Clearance Time (CL) value of 54.67 ± 4.86 ml/hr; a Mean Residence Time (MRT) value of 0.465 ± 0.13 hours; and a Volume Distribution Under Steady State (V_{ss}) value of 25.43 ± 5.2 ml/hr.

94. A pharmaceutical composition according to claim 85, having a pH of between 6.0 to 8.5.

95. A process for preparation of the pharmaceutical composition of poorly water-soluble drugs or compounds in nanoparticulate form according to claim 85 comprising the steps of :

i) Preparation of the drug/compound concentrate, comprising dissolving the poorly water-soluble drug or compound in a suitable water-miscible solvent, or mixtures thereof;

ii) Preparation of an aqueous concentrate of the polymer and pharmaceutically acceptable excipients, comprising the steps of;

a) first addition of the requisite amount of the polymer of formula (I), of high purity and substantially free of monomeric contaminants, specially having a level of toxic NIPAM and VP <0.001 % to an appropriate quantity of water-for-injection to obtain a solution;

b) addition of pharmaceutically acceptable excipients and a buffering agent to the solution of the polymer in water;

iii) Mixing the solution of step ii b) with a diluting fluid to get a clear solution;

iv) Utilization of a needle having an internal diameter of between 0.305 to 0.356 mm, for addition of a smaller volume of solution of step i) to the solution of step iii) 4 seconds; or

v) Utilization of a needle having an internal diameter of between 0.559 to 0.711 mm, for addition of a larger volume of the solution of step i) to the solution of step iii) within 10 seconds;

vi) Injection of the solution of step i) to the solution of step iii), wherein the needle of the syringe through which the solution of step i) is added shall remain dipped in the solution of step iii); and

vii) Optionally, keeping the container containing the solution of step iii) in an inverted position during injection of the solution of step i).

96. A process according to claim 95 wherein the poorly water-soluble drugs used are those as given in preceding claims 68-79.

97. A process according to claim 95 wherein the pharmaceutically acceptable excipients used are those as given in the preceding claims 81-83.

98. A process according to claim 95 wherein the water-miscible solvents are those as given in the preceding claim 80.

99. A process according to claim 95 wherein the diluting fluids used are those as given in the preceding claim 89.

100. A process according to claim 95 wherein the smaller volume of solution, according to step iv), referring to a volume of between 1-5 ml of the solution of step i) of claim 95.

101. A process according to claim 95 wherein the larger volume of solution, according to step v), referring to a volume of between 10-15 ml of the solution of step i) of claim 95

102. A process according to claim 95 wherein the particle sizes of the poorly water-soluble drugs or compounds entrapped within the polymeric shell in the pharmaceutical composition obtained are in the range of 30 to 150 nm.

103. The pharmaceutical composition according to claim95, administrated to patients in need thereof intravenously, intramuscularly, or subcutaneously.

104. The pharmaceutical composition according to claim95, wherein the polymer utilized therein is of high purity; having structure of formula (I); and containing monomeric VP and NIPAM in amounts less than 0.001%, which is safe and non-toxic for human/animal administration.

105. The pharmaceutical composition according to claim95, useful for treatment of pathological conditions, which the poorly water-soluble drugs or compounds of claims 68-79 are capable of.

106. A method of treatment of pathological conditions in humans/animals, which the poorly water-soluble drugs or compounds of claims 68-79 are capable of, comprising administration of a nanoparticulate pharmaceutical composition of the said poorly water-soluble drugs or compounds of claim 85.

107. A method of according to claim 106, comprising of intravenous, intramuscular, or subcutaneous injections.

CLAIMS

The invention claimed is:

1. A polymer comprising of three monomeric units, consisting of 1-Vinylpyrrolidone (VP), N-Isopropylacrylamide (NIPAM), and ester of Maleic anhydride and Polyethylene glycol (MPEG), cross-linked with a bi-functional vinyl derivative, of high purity and substantially free of respective toxic monomeric contaminants;
containing toxic 1-Vinylpyrrolidone (VP) in amounts less than 0.001%;
containing toxic N-Isopropylacrylamide (NIPAM) in amounts less than 0.001%; and
wherein the toxic monomeric contaminants have been removed by filtration of the polymer through a polyethersulphone membrane followed by diafiltration.

2. A polymer of high purity according to claim 1, wherein the bi-functional vinyl cross-linking agent is N,N'-Methylene bis acrylamide (MBA).

3. A polymer according to claim 1, wherein the weight ratio of the monomers, NIPAM:VP is in the range of between 55:22 to 65:35.

4. A polymer according to claim 3, wherein the weight ratio of the monomers, NIPAM:VP is in the range of between 58:32 to 62:28.

5. A polymer according to claim 1, wherein the weight ratio of monomers, (NIPAM+VP):MPEG is in the range of between 90:10 to 95:5.

6. A polymer according to claim 5, wherein the weight ratio of monomers, (NIPAM+VP):MPEG is in the range of between 80:20 to 95:5.

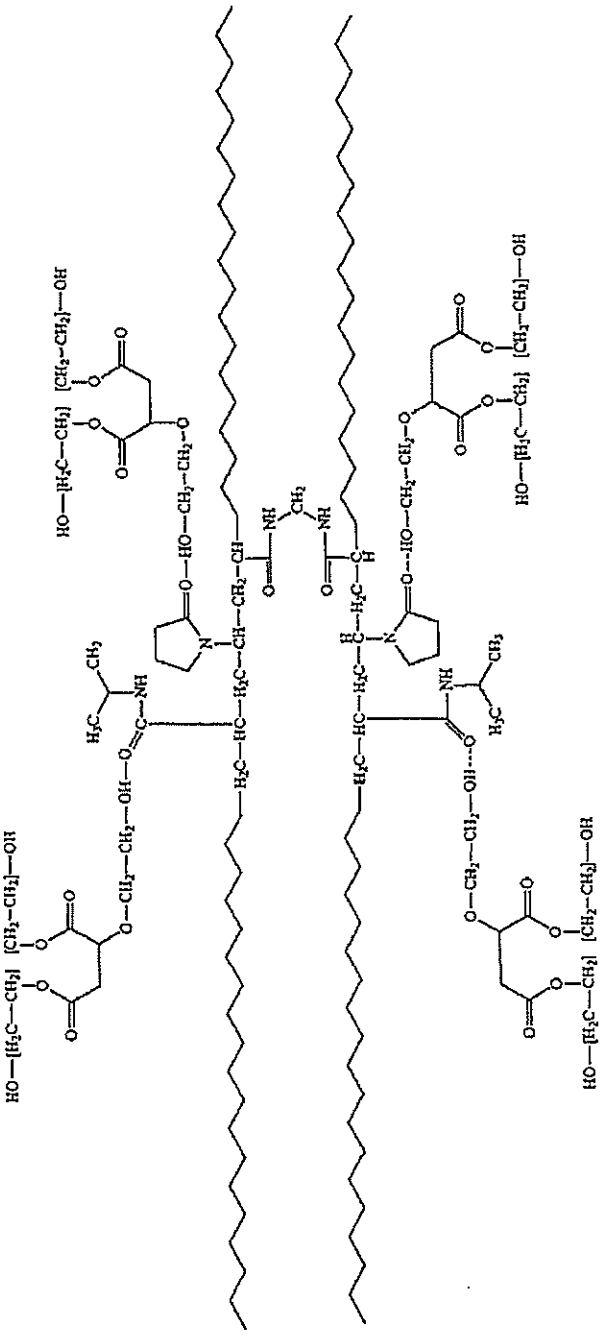
7. A polymer according to claim 1, having peaks of δ at 174, 76.6-77.6, 70.6, 41.6, 31.8, and 22.6 in their ^{13}C NMR spectrum.

8. A polymer according to claim 1, having peaks of δ at 1.14, 1.45, 1.63, 1.99, 2.36, 3.0, 3.23, 3.62-3.66, 3.72, and 3.97 in their ^{1}H NMR spectrum.

9. A polymer according to claim 1, having frequency of values cm^{-1} at as 3500, 3296, 2972-2933, 1546, 1387, 1367, and 1172-1129 in their FT-IR spectrum.

10. A polymer according to claim 1, having structure of formula (I),

(I)



11. A polymer according to claim 1, which is biocompatible.

12. A polymer according to claim 1, which is non-biodegradable.

13. A polymer according to claim 1, which is non-toxic.

14. A polymer according to claim 1, having a $T_{1/2}$ (K10) value of 0.152±0.018 hours.

15. A polymer according to claim 1, having $T_{1/2}$ (α) value of 0.065±0.014 hours.

16. A polymer according to claim 1, having a $T_{1/2}$ (β) value of 0.448±0.0157 hours.

17. A polymer according to claim 1, having a C_{max} value of 82.96±5.11 μg/ml.

18. A polymer according to claim 1, having an Area Under the Curve (AUC) value of 18.29±1.62 hoursxμg/ml.

19. A polymer according to claim 1, having a Clearance Time (CL) value of 54.67±4.86 ml/hr.

20. A polymer according to claim 1, having a Mean Residence Time (MRT) value of 0.465±0.13 hours.

21. A polymer according to claim 1, having a Volume Distribution Under Steady State (V_{ss}) value of 25.43±5.2 ml/hr.

22. A polymer according to claim 1, which is eliminated from urine, faeces, tissues, and rinse.

23. A polymer according to claim 1, which is predominantly eliminated from urine and faeces.

24. A polymer according to claim 1, about 67% of which is eliminated from urine 48 hours post dosing.

25. A polymer according to claim 1, about 17% of which is eliminated from faeces 48 hours post dosing.

26. A polymer according to claim 1, about 84% of which is eliminated from urine, faeces, tissues and rinse, 48 hours post dosing.

27. A polymer according to claim 1, which does not cause any local toxicity at the site of administration, 48 hours post subcutaneous administration of an aqueous solution of the said polymer in a rabbit ear.

28. A polymer according to claim 1, which does not cause any local toxicity at the site of administration, 24 hours post intravenous administration of an aqueous solution of the said polymer in a rabbit ear vein.

29. A polymer according to claim 1, which does not cause any general toxicity, when administrated through an intravenous bolar route to Wistar rats up to five consecutive days at a dose of between 400 mg/kg to 800 mg/kg.

30. A polymer according to claim 1, which does not cause any significant haematological toxicity, when administrated through an intravenous bolar route to Wistar rats up to five consecutive days at a dose of between 400 mg/kg to 800 mg/kg.

31. A [^{14}C]-labelled polymer comprising of three monomeric units, selected from 1-Vinylpyrrolidone (VP), N-Isopropylacrylamide (NIPAM), and ester of Maleic anhydride and Polyethylene glycol (MPEG), cross-linked with N,N'-Methylene bis acrylamide (MBA).

32. A [^{14}C]-labelled polymer comprising of three monomeric units, selected from 1-Vinylpyrrolidone (VP), N-Isopropylacrylamide (NIPAM), and ester of Maleic anhydride and Polyethylene glycol (MPEG), cross-linked with N,N'-Methylene bis acrylamide (MBA).

33. A [^{14}C]-labelled polymer of high purity according to claim 31, wherein the weight ratio of the monomers, NIPAM:VP is in the range of between 55:22 to 65:35, and the ratio of monomers, (NIPAM+VP):MPEG is in the range of between 90:10 to 95:5.

34. A [^{14}C]-labelled polymer of high purity according to claim 31, wherein the weight ratio of the monomers, NIPAM:VP is in the range of between 58:32 to 62:28, and the ratio of monomers, (NIPAM+VP):MPEG is in the range of between 80:20 to 95:5.