CLAIMS

1. A pharmaceutical composition comprising:

(a) two or more neo-antigenic peptides or pharmaceutically acceptable salts thereof;

(b) a pH modifier, in which the pH modifier is succinate or citrate;

(c) a tonicity adjusting agent selected from the group consisting of dextrose, trehalose and sucrose; and

(d) a pharmaceutically acceptable carrier;

in which each of the two or more neo-antigenic peptides or pharmaceutically acceptable salts thereof has an isoelectric point (Pi) and hydrophobicity (HYDRO) of Pi ≥5 and HYDRO ≥-6.0, Pi ≥8 and HYDRO ≥-8.0, Pi ≤5 and HYDRO ≥-5, or Pi ≥9 and HYDRO ≤-8.0; and

in which the two or more neo-antigenic peptides are soluble in the pharmaceutical composition.

2. A pharmaceutical composition according to Claim 1, in which the pharmaceutical composition is a vaccine composition.

3. A pharmaceutical composition according to Claim 1 or 2, in which the pharmaceutical composition comprises from two to forty neo-antigenic peptides.

4. A pharmaceutical composition according to Claim 1, 2 or 3, in which the pharmaceutical composition comprises from two to five neo-antigenic peptides.

5. A pharmaceutical composition according to any preceding claim, in which each of the neo-antigenic peptides or pharmaceutically acceptable salts thereof has an isoelectric point (Pi) and hydrophobicity (HYDRO) of: Pi ≥5 and HYDRO ≥-6.0, Pi ≥8 and HYDRO ≥-8.0, Pi ≥9 and HYDRO ≤-8.0, or Pi >7 and HYDRO ≥-5.

6. A pharmaceutical composition according to any preceding claim, in which the neo-antigenic peptides each range from 5 to 50 amino acids in length.

7. A pharmaceutical composition according to any preceding claim, in which the pH modifier is a tricarboxylate salt.

8. A pharmaceutical composition according to any preceding claim, in which the pH modifier is a dicarboxylate salt.

9. A pharmaceutical composition according to any preceding claim, in which the pH modifier is citrate or a pharmaceutically acceptable salt thereof.

10. A pharmaceutical composition according to any preceding claim, in which the pH modifier is present at a concentration from 1 mM to 10 mM.

11. A pharmaceutical composition according to any preceding claim, in which each of the two or more neo-antigenic peptides or pharmaceutically acceptable salts thereof has an isoelectric point (Pi) and hydrophobicity (HYDRO) of: Pi >7 and HYDRO ≥-5.5, Pi ≥8 and HYDRO ≥-8.0, Pi ≤5 and HYDRO ≥-5, or Pi ≥9 and HYDRO ≤-8.0.

12. A pharmaceutical composition according to any preceding claim, in which the pharmaceutically acceptable carrier further comprises dimethylsulfoxide.

13. A pharmaceutical composition according to any preceding claim, in which the pharmaceutical composition further comprises an immunomodulator or adjuvant.

14. A pharmaceutical composition according to any preceding claim, in which each of the neo-antigenic peptides or pharmaceutically acceptable salts thereof are each present at an amount of from 10 to 500 μg/ml.

15. A method of selecting a neo-antigenic peptide for incorporation into an aqueous formulation, the method comprising:

(a) predicting the solubility of a neo-antigenic peptide in an aqueous formulation in which predicting comprises determining whether the combined isoelectric point (Pi) and hydrophobicity (HYDRO) of the neo-antigenic peptide is bounded by Pi ≥5 and HYDRO ≥-6.0; Pi ≥8 and HYDRO ≥-8.0; Pi ≤5 and HYDRO ≥-5; Pi ≥9 and HYDRO ≤-8.0; or Pi >7 and a HYDRO value of ≥-5.5; and

(b) selecting the neo-antigenic peptide and incorporating into the aqueous formulation when the combined Pi and HYDRO of the neo-antigenic peptide is bounded by Pi ≥5 and HYDRO ≥-6.0, Pi ≥8 and HYDRO ≥-8.0, Pi ≤5 and HYDRO ≥-5, Pi ≥9 and HYDRO ≤-8.0, or Pi >7 and a HYDRO value of ≥-5.5..

16. A vaccination or immunization kit comprising:

(a) a separately packaged freeze-dried immunogenic composition comprising two or more neo-antigenic peptides or pharmaceutically acceptable salts thereof; and

(b) a solution for the reconstitution of the freeze-dried immunogenic composition,

in which each of the two or more neo-antigenic peptides or pharmaceutically acceptable salts thereof has a Pi ≥5 and HYDRO ≥-6.0, Pi ≥8 and HYDRO ≥-8.0, Pi ≤5 and HYDRO ≥-5, Pi ≥9 and HYDRO ≤-8.0 or Pi >7 and HYDRO ≥-5.5.

17. A method according to Claim 15, in which the neo-antigenic peptide ranges from 5 to 50 amino acids in length, 15 to 35 amino acids in length, 15 to 24 amino acids in length, 6 to 25 amino acids in length, 9 to 15 amino acids in length, 8 to 11 amino acids in length, or 9 or 10 amino acids in length.

18. A method according to Claim 15 or 17, in which the aqueous formulation comprises a pH modifier.

19. A method according to Claim 18, in which the pH modifier is a base.

20. A method according to any of Claims 15 to 19, in which the pH modifier is a dicarboxylate or tricarboxylate salt.

21. A method according to any of Claims 15 to 20, in which the pH modifier is succinate.

22. A method according to any of Claims 15 to 20, in which the pH modifier is citrate.

23. A method according to any of Claims 15 to 21, in which the pH modifier is sodium succinate.

24. A method according to Claim 21, in which succinate is present in the aqueous formulation at a concentration from 1 mM to 10 mM.

25. A method according to Claim 21, in which succinate is present in the aqueous formulation at a concentration from 2 mM to 5 mM.

26. A method according to any of Claims 15 to 25, in which the aqueous formulation comprises dextrose, sucrose or trehalose.

27. A method according to any of Claims 15 to 26, in which the aqueous formulation further comprises dimethylsulfoxide.

28. A method according to any of Claims 15 to 27, in which the aqueous formulation comprises 5% dextrose in water and 5mM succinate.

29. A method of preparing a neo-antigenic peptide solution for a neoplasia vaccine, the method comprising:

(a) preparing a solution by selecting at least one neo-antigenic peptide for incorporation into an aqueous formulation according to any preceding claim; and

(b) combining the solution comprising the at least one neo-antigenic peptide or a pharmaceutically acceptable salt thereof with a solution comprising succinic acid or citric acid or a pharmaceutically acceptable salt thereof, thereby preparing a peptide solution for a neoplasia vaccine.

30. A method according to Claim 29, in which the pharmaceutically acceptable salt of succinic acid or citric acid is present in the peptide solution at a concentration from 1 mM to 10 mM.

31. A method according to Claim 29 or 30, in which the peptide solution for a neoplasia vaccine comprises at least two, at least three, at least four or at least five neo-antigenic peptides.

32. A method according to Claim 29, 30 or 31, in which the peptide solution for a neoplasia vaccine comprises water, dextrose, succinate and dimethylsulfoxide.

33. A method according to any of Claims 29 to 32, in which the peptide solution for a neoplasia vaccine is lyophilizable.

34. A method according to any of Claims 29 to 33, in which the method further comprises, after the step of combining, filtering the peptide solution for a neoplasia vaccine.

35. A method of preparing a neoplasia vaccine, the method comprising:

(a) preparing a peptide solution according to any of Claims 29 to 34; and

(b) combining the peptide solution with a solution of an immunomodulator or adjuvant, thereby preparing a neoplasia vaccine.

36. A method according to Claim 35, in which the immunomodulator or adjuvant is selected from the group consisting of poly-ICLC, 1018 ISS, aluminum salts, Amplivax, AS15, BCG, CP-870,893, CpG7909, CyaA, dSLIM, GM-CSF, IC30, IC31, Imiquimod, ImuFact IMP321, IS Patch, ISS, ISCOMATRIX, Juvlmmune, LipoVac, MF59, monophosphoryllipid A, Montanide IMS 1312, Montanide ISA 206, Montanide ISA 50V, Montanide ISA-51, OK-432, OM-174, OM-197-MPEC, ONTAK, PepTel®, vector system, PLGA microparticles, resiquimod, SRL172, Virosomes and other Virus-like particles, YF-17D, VEGF trap, R848, beta-glucan, Pam3Cys, and Aquila's QS21 stimulon.