claims

1. A purified preparation of infectious *Plasmodium*-species sporozoites from mosquito salivary glands comprising less than 85 nanograms of mosquito SGM (salivary gland material) per 25,000 sporozoites, as measured by ELISA by using rabbit anti-SGM serum as primary antibody and alkaline phosphatase-conjugated anti-Rabbit IgG as secondary antibody.

2. The purified preparation of claim 1 additionally comprising an excipient, and comprising less than 15 nanograms of mosquito SGM per 25,000 sporozoites, less than 1 nanogram of mosquito SGM per 25,000 sporozoites, or less than 0.12 nanograms of mosquito SGM per 25,000 sporozoites, as measured by ELISA by using rabbit anti-SGM serum as primary antibody and alkaline phosphatase-conjugated anti-Rabbit IgG as secondary antibody.

3. The purified preparation of claim 1 or claim 2 wherein said sporozoites are purified from a pre-purification preparation of mosquito salivary gland material in which at least 98% of mosquito SGM has been removed from said pre-purification preparation, at least 99.9% of mosquito SGM has been removed from said pre-purification preparation, or at least 99.97% of mosquito SGM has been removed from said pre-purification preparation.

4. The purified preparation of any of claims 1-3 prepared aseptically.

5. The purified preparation of any of claims 1-4 wherein said sporozoites contain one or more transgenes.

6. The purified preparation of any of claims 1-5 wherein the species of said *Plasmodium*-species sporozoite is chosen from the group consisting of *P. falciparum, P. vivax, P. malariae, P. knowlesi and P. ovale.*

7. The purified preparation of any of claims 1-6 wherein said sporozoites are sufficiently attenuated such that subsequent to infection of a host, said parasites fail to cause disease pathology of malaria and wherein said attenuation is established by introduction of a heritable genetic alteration or gene mutation, or by radiation exposure, chemical exposure, or environmental exposure.

8. The purified preparation of claim 7 wherein attenuation is established by radiation exposure and where said radiation exposure is at least 100 Gy, but no more than 1000 Gy of radiation or wherein said radiation exposure is 150 Gy.

9. The purified preparation of claim 7 or 8 for use in conferring protective immunity against malaria induced by a *Plasmodium*-species parasite infection of a human or other mammalian host, said use comprising administration of at least one dose of the purified preparation of metabolically active attenuated sporozoites; wherein said purified preparation is prepared aseptically, and wherein pathological manifestations of said malaria are prevented in said host upon subsequent exposure to pathogenic parasites of said *Plasmodium*-species.

10. The purified preparation for use according to claim 9, said use comprising administration of at least two or at least three doses of said preparation.

11. The purified preparation of any of claims 1-6 for use in conferring protective immunity against malaria induced by a *Plasmodium*-species parasite infection in a human or other mammalian host, said use comprising administration of a regimen of an antimalarial drug concurrent with the administration of at least one dose of the purified preparation of aseptically prepared pathogenic sporozoites of said *Plasmodium*-species, wherein protective immunity is conferred in said human or other mammalian host and pathological manifestations of said malaria are prevented.

12. The purified preparation for use according to claim 11, wherein said antimalarial drug is chloroquine.

13. A method for purification of metabolically active *Plasmodium* sporozoites, said method comprising:

a. providing an aqueous pre-purification preparation derived from the salivary glands of mosquitoes comprising *Plasmodium* sporozoites and non-sporozoite material specific to the salivary glands of mosquitoes;

b. passing said pre-purification preparation sequentially through a set of size exclusion filters comprising:

i) a first matrix filter with a nominal pore size of 5 to 20 microns;

ii) a second matrix filter with a nominal pore size of 0.6 to 1.2 microns;

iii) a third track-etched membrane filter with a pore size of 1.2 to 3.0 microns;

c. collecting said purified sporozoite preparation on a dead-end filtration collecting filter with a pore size capable of retaining said sporozoites; and

d. removing said purified sporozoite preparation from the collecting filter; wherein said purified sporozoite preparation comprises less than 85 ng of non-sporozoite material specific to the salivary glands of mosquitoes per 25,000 sporozoites, as measured by ELISA by using rabbit anti-SGM serum as primary antibody and alkaline phosphatase-conjugated anti-Rabbit IgG as secondary antibody.

14. The method of claim 13 wherein said first, second and third filters are sequentially connected in a system wherein said sporozoites pass across said filters with a flux.

15. The method of claim 14 wherein said system has a flux of at least 3 L/hr/m^2 but no more than 1500L/hr/m^2, or at least 125 L/hr/m^2 but no more than 250 L/hr/m^2.

16. The method of any of claims 13-15 wherein said first filter has a nominal pore size of 10 microns.

17. The method of any of claims 13-16, wherein said second filter has a nominal pore size 0.6 microns.

18. The method of any of claims 13-17, wherein said third filter has a pore size of 1.2 microns.

19. The method of any of claims 13-18, wherein said collection filter has a pore size of 0.4 microns.

20. The method of any of claims 13-19, wherein said purified preparation comprises less than 85 nanograms of said material per 25,000 sporozoites, less than 15 nanograms of said material per 25,000 sporozoites, less than 1 nanogram of said material per 25,000 sporozoites, or less than 0.12 nanograms of said material per 25,000 sporozoites.

21. The method of any of claims 13-20, wherein at least 98% of said material has been removed from pre-purification preparation, at least 99.9% of said material has

been removed from pre-purification preparation, or at least 99.97% of said material has been removed from pre-purification preparation.