

**[0069]** The liposome self-assembly method described herein may be used to provide liposomes for in vivo applications and for on-demand drug encapsulation and delivery and may be scaled up or down providing microfluidics devices or larger production scale devices.

**[0070]** From the foregoing description, one skilled in the art may ascertain the essential characteristics of this invention and, without departing from the spirit and scope thereof, may make various changes and modifications of the invention to adapt it to various usages and conditions.

1. A device configured for the formation of vesicles comprising:

a fluid introduction zone and a vesicle formation zone;  
said fluid introduction zone comprising a first outlet and a second outlet configured and disposed to provide parallel flow of an outer flow stream, flowing from said first outlet, sheathing an inner flow stream, flowing from said second outlet; and

said vesicle formation zone being configured and disposed to receive a parallel flow of the outer flow stream, flowing from said first outlet, sheathing the inner flow stream, flowing from said second outlet, and configured for a controlled and substantially uniform dispersion of an organic material, flowing in the inner flow stream, at a plane perpendicular to said vesicle formation zone, and said vesicle formation zone having an outlet.

2. The device for the formation of vesicles of claim 1 wherein said fluid introduction zone comprises a central feed line and an outer longitudinally extending sheath, said outer longitudinally extending sheath having an inner diameter greater than an outer diameter of said central feed line, said central feed line having said first outlet centrally disposed in said outer longitudinally extending sheath.

3. The device for the formation of vesicles of claim 2 wherein said fluid introduction zone further comprises a plurality of outer feed lines disposed adjacent an inner surface of said outer longitudinally extending sheath, each said plurality of outer feed lines having a terminating end in a plane substantially perpendicular to said outer longitudinally extending sheath and each being configured for a flow through of an aqueous stream, said first outlet of said fluid introduction zone comprising said terminating ends of said plurality of outer feed lines.

4. The device for the formation of vesicles of claim 3 wherein said first outlet of said fluid introduction zone is at a distance from said outlet of said vesicle formation zone greater than or equal to a distance of said second outlet of said fluid introduction zone from said outlet of said vesicle formation zone.

5. The device of claim 1 wherein said vesicle formation zone is configured for a flow through of an organic stream, flowing from said second outlet of said fluid introduction zone, at a volumetric flow rate less than or equal to a volumetric flow rate of an aqueous stream, flowing from said first outlet of said fluid introduction zone.

6. The device of claim 1 wherein said second outlet of said fluid introduction zone has an inner diameter of at most 255  $\mu\text{m}$ .

7. The device of claim 1 configured for a flow rate ratio of a flow from said first outlet of said fluid introduction zone to a flow from said second outlet of said fluid introduction zone between about 500:1 to about 10000:1.

8. The device of claim 2 wherein said outer sheath has an inwardly tapered portion, proximate said second outlet of said

fluid introduction zone, and a longitudinally extending portion, extending from said inwardly tapered portion to said outlet of said vesicle formation zone.

9. The device of claim 8 wherein said second outlet is movable about the longitudinal axis of said outer sheath, with respect to said inwardly tapered portion of said outer sheath.

10. The device of claim 1 wherein said vesicle formation zone is annular.

11. A process for the formation of vesicles comprising the steps of:

flowing an aqueous stream;  
flowing an organic stream centrally into and parallel with the flow of the aqueous stream, whereby the aqueous stream completely sheaths the organic stream;  
dispersing a miscible organic material, flowing in the organic stream, with the aqueous stream; and  
forming vesicles.

12. The process of claim 11 wherein said steps of flowing an aqueous stream and flowing an organic stream comprises flowing the aqueous stream and the organic stream at a flow rate ratio between about 500:1 to about 10000:1.

13. The process of claim 12 further comprising a step of moving an outlet of the organic stream about a longitudinal axis of a sidewall, through which the aqueous stream is flowing, with respect to an inwardly tapered portion of the sidewall.

14. A device configured for the formation of vesicles comprising:

a longitudinally extending sheath configured and disposed for the flowthrough of an aqueous stream and a parallel flowing organic stream, said longitudinally extending sheath comprising:

an aqueous stream inlet configured and disposed to receive the aqueous stream into said sheath;  
an organic stream inlet configured and disposed to receive a parallel flowing organic stream centrally within the aqueous stream; and  
an outlet.

15. The device for the formation of vesicles of claim 14 wherein said aqueous stream inlet is at a distance greater than or equal to a distance of said organic stream inlet, from said outlet of said sheath.

16. The device for the formation of vesicles of claim 14 wherein said aqueous stream inlet is configured for a first volumetric flow rate and said organic stream inlet is configured for a second volumetric flow rate of an aqueous stream, said first volumetric flow rate is greater than or equal to said second volumetric flow rate.

17. The device for the formation of vesicles of claim 14 wherein said organic stream inlet has an inner diameter of at most 255  $\mu\text{m}$ .

18. The device for the formation of vesicles of claim 16 configured for a flow rate ratio of the first volumetric flow rate to the second volumetric flow rate between about 500:1 to about 10000:1.

19. The device for the formation of vesicles of claim 14 wherein said longitudinally extending sheath is annular.

20. The device for the formation of vesicles of claim 14 wherein said longitudinally extending sheath has an inwardly tapered portion, proximate said organic stream inlet, and a longitudinally extending portion, extending from said inwardly tapered portion to said outlet, said organic stream inlet being movable about a longitudinal axis of said outer sheath, with respect to said inwardly tapered portion.