Stability and Reconstitution Testing of Investigational Syphilis Vaccine Adjuvant

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Adjuvants are important components of complete vaccines designed to stimulate the immune system to mount a robust response to the main antigen. The adjuvant studied here is PAI-sRI TLR 1/2,4, an emulsion adjuvant that, paired with antigens from the syphilis-causing bacterium *Treponema pallidum*, is being tested in a potential syphilis vaccine. Adjuvants are lyophilized, essentially freeze dried, to increase stability for transport and storage. In order to be combined with the antigen, lyophilized PAI-sRI TLR 1/2,4 must be reconstituted back into liquid form. Reconstitution of PAI-sRI TLR 1/2,4 yields a product much larger than originally manufactured and with a particle size too variable for effective use. We hypothesized that vigorous mixing, called vortexing, would likely be needed to dissociate the adjuvant material and return it to an average particle size and range (PDI) resembling the original (pre-lyophilization) product. PAI-sRI TLR 1/2,4 was reconstituted and passed through a series of experiments, testing multiple vortexing time points and rest periods in order to ensure desirable PDI and particle size. It was found that a 5 minute vortexing time produced the best results, closest to the manufactured product pre-lyophilization. It was also found that the adjuvant was stable for at least 6 hours at room temperature with a high likelihood of remaining stable even longer. This research has shown that PAI-sRI TLR 1/2,4 will be properly sized for an extended period of time post reconstitution as a part of this investigational syphilis vaccine.