

Stabilizing micronized particles boosts sterility and safety of vaccines

Jessica M.H. Thrall^{1,2}, Stephen P. Cape^{1,2}, Nisha K. Shah^{1,2}, Scott Winston¹, David H. McAdams², Diane E. Griffin³, Wen-Hsuan Lin³ and Robert E. Sievers^{1,2}

¹Aktiv-Dry LLC, 2100 Central Avenue, USA

²University of Colorado Boulder, USA

³Johns Hopkins Bloomberg School of Public Health, Molecular Microbiology and Immunology, USA

Current vaccine delivery methods for prevention of global childhood diseases carry a high risk for needle contamination, vaccine wastage, and transportation and storage difficulties. Aktiv-Dry LLC's focus is on R&D of safe and effective microparticles of vaccines and pharmaceuticals for easier storage, greater thermal stability, and ease of use. We utilize our patented CO₂-Assisted Nebulization with a Bubble Dryer® (CAN-BD) system to create stable dry microparticles of compounds for administration by needle-free aerosol inhalers, sublingual solid formulations, or safer unit-dose, all-in-one auto-reconstitution syringe devices.

Recently, our work has focused on vaccine prevention of measles and hepatitis B. Aktiv-Dry has developed inhalable and sublingual vaccines for measles along with a human-powered, active dry powder inhaler called the PuffHaler® for intrapulmonary delivery of the dry powder measles vaccine. CAN-BD processed measles vaccine shelf-life stability has been shown for 4 years at 2-8°C, protective immunity after intrapulmonary delivery to rhesus macaques, and no serious adverse events reported to date during on-going clinical Phase I safety trials in 60 adult males in India.

We have also demonstrated stability of CAN-BD processed and dried microparticles of hepatitis B vaccine for use in a pre-loaded, single-dose, field-reconstitution device for parenteral delivery. Aktiv-Dry-formulated hepatitis-B vaccine was stabilized with trehalose, processed, and determined to retain stability using in-house stability assays. Our immunogenicity results from intrapulmonary mucosal membrane delivery of measles vaccine dry powder aerosols and fundamental project goals may be extended to prevention and treatment (e.g., antibiotics and antivirals) of other pulmonary diseases (e.g., tuberculosis and influenza).

Biography

Jessica Thrall earned her Ph.D. in Biochemistry from the University of Colorado in 2012. Jessica spent nearly three years researching *Mycobacterium Tuberculosis* initial and chronic infection stages, and testing novel vaccines and drugs using small animal models at the Mycobacteria Research Laboratories at Colorado State University. As part of the Aktiv-Dry LLC's science team, Jessica drives the biological assay development sector for stability and efficacy testing of dry powders produced using the CAN-BD process. Jessica brings to Aktiv-Dry her background in vaccine and drug testing in animal models and her previous work involving innovative assay development and protein formulation.

jthrall@aktiv-dry.com