

# DEVELOPMENT OF STABILIZING FORMULATIONS OF A TRIVALENT INACTIVATED POLIOVIRUS VACCINE IN A DRIED STATE FOR DELIVERY IN THE NANOPATCH™ MICROPROJECTION ARRAY

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The worldwide switch to inactivated polio vaccines (IPV) is a key component of the overall strategy to achieve and maintain global polio eradication. To this end, new IPV vaccine delivery systems may enhance patient convenience and compliance. In this work, we examine Nanopatch™ (a solid, polymer micro-projection array) which offers potential advantages over standard needle/syringe administration including intradermal delivery and reduced antigen doses. Using trivalent IPV (tIPV) and a purpose-built evaporative dry-down system, candidate tIPV formulations were developed to stabilize tIPV during the drying process and upon storage. Identifying conditions to minimize tIPV potency losses during rehydration and potency testing was a critical first step. Various classes and types of pharmaceutical excipients (~50 total) were then evaluated to mitigate potency losses (measured through D-antigen ELISAs for IPV1, IPV2, and IPV3) during drying and storage. Various concentrations and combinations of stabilizing additives were optimized in terms of tIPV potency retention, and two candidate tIPV formulations containing a cyclodextrin and a reducing agent (e.g., glutathione), maintained ≥80% D-antigen potency during drying and subsequent storage for 4 weeks at 4°C, and ≥60% potency for 3 weeks at room temperature with the majority of losses occurring within the first day of storage.

## References:

\* Wan, Y., et al. (in press), *Development of Stabilizing Formulations of a Trivalent Inactivated Poliovirus Vaccine in a Dried State for Delivery in the Nanopatch™ Microprojection Array*. Journal of Pharmaceutical Sciences. 2018.

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