HISTORY AND DEVELOPMENT OF A LIQUID FORMULATION FOR ADENOVIRAL VACCINES

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The road to developing a stable liquid formulation for a live virus is burdened with challenges requiring a tailored methodology while complying with the target product profile, especially regarding storage temperature. The approach described here yielded a stable Adenovirus-based vaccine stored in frozen state for early stage development, and an improved formulation that allows storage in the liquid state at 2-8°C for late stage development.

In short, formulation components were initially screened and selected according to their stabilizing potential. Subsequently, according to Quality by Design (QbD) principles, a Design of Experiments (DOE) screening was used to define the specifications for each component of the formulation (excipients, pH, API). The resulting early stage formulation was implemented in CTM manufacturing of Adenoviral vaccines with storage and distribution at ≤-65°C. This formulation guarantees stability during storage and at accelerated conditions and allows great flexibility outside the normal temperature range of a standard clinical trial.

For late stage development of a vaccine a storage temperature above zero is highly recommended. A more unorthodox methodology was applied to develop the first formulation for Adenoviruses that allows storage in the liquid state. With this formulation it is now possible to stabilize the Adenovirus-based vaccines for at least 2 years at 2-8°C. Results are so encouraging that this new formulation will be implemented in CTM manufacturing. This means a significant step in developing temperature-stable and affordable vaccines that can now be stored in the vast quantities required to prevent and eradicate infectious diseases across the world.