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# Gyrolab-Based In Vitro Immunoassay for Potency and Quality Control of Chikungunya VLP Vaccine: A Sensitive Alternative to Animal Models

As the regulatory standards move toward replacing animal-based safety assays, robust in vitro methods form the foundation of vaccine quality control.

VIMKUNYA is a single dose vaccine containing highly purified Chikungunya virus-like particles (CHIKV VLP) produced in a cell line and adjuvanted with aluminium.

While pre-clinical and early development data were generated using in vivo experiments, routine quality control of the vaccine aimed to solely rely on animal-free tests. Monoclonal antibodies can be suitable for assessing key quality attributes and ensure comparability of commercial batches to those originally demonstrated to be safe and efficacious in clinical studies.

Due to interference from the adjuvant, biolayer interferometry (BLI) was not suitable for measuring vaccine potency. Therefore, an automated in vitro assay using microfluidic in nanoliter-scale was established to quantify intact epitopes relative to total protein.

This sandwich immunoreactivity assay utilizes well characterized CHIKV specific neutralizing antibodies—biotinylated mAb 10-18 for capture and AF-647 conjugated mAb 242-5 for detection.

Parallel studies comparing the in vitro assay to the mouse immunogenicity model, by testing formulations with decreasing protein concentration, demonstrated a similar dose-dependent response. Additionally, accelerated temperature studies indicated a good correlation between the in vivo and in vitro assay. These experiments demonstrated that the in vitro immunoassay has greater analytical sensitivity compared to mouse immunogenicity model and can detect small changes in product quality before they become biologically significant.

These findings confirm that the in vitro assay reliably detects varying amounts of immunologically relevant epitopes, accurately reflecting the intended biological activity of the CHIKV VLP vaccine. This provides rationale for quality control exclusively based on the in vitro assay, while product potency is represented by the ratio of immunoreactivity (as measured by the microfluidic assay presented) to total protein concentration