Poster

K-Vax vaccine : antigen characterization and lot release assay

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ABSTRACT

Klebsiella pneumoniae is directly responsible for more than 650.000 deaths each year worldwide (1) due to its high level of antibiotic resistance (2) having an impact on public health and economy (1). Protecting the vulnerable population with vaccination is one of the solutions called by the World Health Organization and partners. Vaxdyn proposes a vaccine candidate, K-Vax, using a chimeric inactivated LPS-null Acinetobacter baumannii cells expressing two K. pneumoniae outer-membrane proteins (OMPs). As part of the analytical methods for characterization of the drug substance, a quantitative Enzyme-Linked Immunosorbent Assay (ELISA) is being developed for quantification of antigen content. For that aim, first monoclonal antibodies (mAb) were generated from hybridomas, after fusion of myeloma cells with the β-lymphocytes producers of the antibodies of interest. Then mAb selected are tested in three different type of quantitative ELISA and the optimal ELISA is selected for each mAb. Finally, the ELISA selected is qualified. As a result of the research, Vaxdyn has generated two specific mAb against two different OMP antigens of the vaccine. Those mAb where characterized and three different types of ELISA were tested for antigen quantification: Competitive, Indirect and Sandwich ELISA. Indirect ELISA was selected as the most suitable for antigen content quantification(3). Indirect ELISA has been qualified based in seven parameters: reproducibility, specificity, linearity, instrumental precision, method precision, intermediate precision, and accuracy. In conclusion, Vaxdyn has developed and qualified two ELISA assays for quantification of OMP antigens present in the K-Vax vaccine.

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