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Detection of an Immunologically-Relevant Epitope in the Heberbiovac® Vaccine Active Pharmaceutical Ingredient Employing CB.Hep-4 Monoclonal Antibody

Tatiana ALVAREZ M. [1], Williams FERRO V. [1], Déborah GEADA L. [2], Yenisley MEDINA S. [1], José MONTERO N. [1], Lázara MUÑOZ H. [3], Yarysel GUEVARA A. [1], Maylín LA O G. [4] & Rodolfo VALDÉS V. [1] *

[1] *Monoclonal Antibody Department,* [3] *Process Control Department,*
[4] *Quality Control Direction. Genetic Engineering and Biotechnology Center. Ave 31 be/158 and 190, Playa, P.O. Box 6162, Havana 10600, Cuba*
[2] *Biology Faculty, Havana University, Street 25, # 455, Havana 10400, Cuba*

***SUMMARY*. The presence of an immunologically-relevant epitope comprised between amino acids 134 and 153 of Heberbiovac® HB vaccine active pharmaceutical ingredient (API) using an enzyme-linked immunosorbent assay (ELISA) based on CB.Hep-4 monoclonal antibody (mAb) was investigated in this study. To reach this main subject, the validation of CB.Hep-4 mAb quantification system was firstly performed. The previously established ELISA to quantify CB.Hep-4 mAb was characterized by short incubation times at high temperature, which is unusual because of poor protein stability under these conditions. The linear range and recovery ranged 3.1-50 ng/mL and 95.2-105.3%, respectively. Maximum intra-and inter-assay variation coefficients were 6.5 and 7.0%, respectively. Thus, CB.Hep-4 mAb was quantified with specificity, precision, accuracy, and without interferences with this immunoassay. Then, several consecutive samples of Heberbiovac® HB API were monitored with CB.Hep-4 mAb, to demonstrate the presence of an immunologically-relevant epitope in this recombinant protein for vaccination.**

KEY WORDS: Hepatitis B vaccine, Monoclonal antibody, Immunoassay.

* Author to whom correspondence should be addressed: *E-mail:* rodolfo.valdes@cigb.edu.cu

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